POLIOMYELITIS VACCINE

UNIVERSITY OF MICHIGAN
JUL 27 1955
MAIN READING ROOM

HEARINGS

BEFORE THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE HOUSE OF REPRESENTATIVES

EIGHTY-FOURTH CONGRESS

FIRST SESSION

ON

POLIOMYELITIS VACCINATION ASSISTANCE LEGISLATION

MAY 25 AND 27, 1955

PART 1

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POLIOMYELITIS VACCINE

WEDNESDAY, MAY 25, 1955

HOUSE OF REPRESENTATIVES,
COMMITTEE ON INTERSTATE AND
FOREIGN COMMERCE,
Washington, D. C.

The committee met, pursuant to call, at 10 a. m., in the committee room, New House Office Building, Hon. J. Percy Priest, chairman, presiding.

The CHAIRMAN. The committee will come to order.

The hearings which will begin today, Wesdesday, May 25, are scheduled to deal primarily with two bills, namely, H. R. 6286, the administration's $28 million poliomyelitis immunization assistance bill, and H. R. 6207, a bill designed to give authority to the Secretary of Health, Education, and Welfare, through an amendment of the biologics control law, to supervise and control, in the interest of protecting and preserving the health of the American people, the distribution and use of biological products.

I have introduced both of these bills.

A companion bill to H. R. 6286, the administration's immunization assistance bill, has also been introduced by Congressman Charles A. Wolverton, Republican, New Jersey, ranking minority member of this committee, being H. R. 6287.

On the surface it might seem as if the subjects covered by H. R. 6286 and H. R. 6207 are related to each other only in an incidental way. A closer study of the bills, however, will make it apparent that the relationship between the two is rather close and direct.

The purpose of this statement is to point up the way in which the subjects covered by these two bills are related to each other and generally to give a proper focus and perspective to these hearings.

The hearings on H. R. 6207 and H. R. 6286 are the first ones to be held by this committee since the Secretary of Health, Education, and Welfare, on April 12, licensed six manufacturers to produce the Salk vaccine. This action was taken by the Secretary under the biologics control law, which may be found in section 361 of the Public Health Service Act.

The events which have occurred between April 12 and the present day are too well known to be repeated in any detail. A summary of these events is contained in the Secretary's report to the President and that summary will probably be brought up to date by one of the witnesses speaking for the Department of Health, Education, and Welfare.

Being the first hearing on a subject on which many, and perhaps too many, statements have been made which have been interpreted by some

people as having a partisan slant, I want to state categorically that this committee never has and I hope never will approach any public health problem in a partisan spirit.

Rather, this committee will seek to approach the problems created by the attempt to secure rapid mass application of the new Salk vaccine in such a way that prompt action may be taken on bills dealing with some of the immediate problems.

On the other hand, this committee would feel derelict in its duties if it failed to give at the same time close attention to the long-range implications of the Salk vaccine situation.

The second point I wish to make is that this committee's interest in and concern with the Salk vaccine situation is not a recent and belated one.

In a sense the hearings this morning are a logical extension of the hearings on poliomyelitis which were held by this committee during the 83d Congress in the fall of 1953.

In the course of those hearings, a presentation was made by a panel of outstanding experts on all major crippling and killing diseases, including polio. Extensive mention was made of Dr. Salk's work on a vaccine which was then being developed at the University of Pittsburgh.

It is interesting at this time to go back to a few statements made then by the experts with regard to polio vaccines and their application.

Dr. Victor H. Haas, Director of the National Microbiological Institute, Public Health Service, made the following statement with regard to the polio vaccine then in a developmental stage:

> * * * It will be our responsibility to make certain that whatever vaccine is offered for use has some evidence of effectiveness and that it is safe for use in humans.
>
> We are prepared to assume this responsibility. Our scientists during the past few years have anticipated that such a situation ultimately would develop, so that they are now preparing themselves to assume responsibility for making certain that whatever vaccines ultimately are to come will conform with the principles of safe and adequate biological products.

When one considers the events which have occurred since April 12, it is well to give renewed attention to the warning given in the course of these hearings by Dr. Albert Sabin of the Children's Hospital Research Foundation, Cincinnati, Ohio. Dr. Sabin spoke of the development of vaccines and made the following statement:

> * * * everybody in the public health field knows that when you reach the point where you can begin to inoculate an agent into millions of children, your problems have only just begun. You have to begin to learn what it does and how to use it.

The prophetic words of Dr. Sabin constitute a fitting preamble to more recent events.

Several weeks before the licensing of the vaccine by the Department of Health, Education, and Welfare, I contacted Dr. Scheele and Dr. Keefer with respect to any plans which the Department might have to provide for allocating the scarce vaccine so that the vaccine would go to those classes of persons where it would do the most good. Also, the question of making the vaccine available to all children, regardless of their parents' ability to pay, was discussed. At that time, I was advised by Dr. Scheele and Dr. Keefer that no legislative action was required.

Two days following the licensing of the vaccine on April 14, 1955,

I addressed a letter to Hon. Oveta Culp Hobby, Secretary of the Department of Health, Education, and Welfare, which summarizes, briefly, the views expressed by Dr. Scheele and Dr. Keefer at that time. The letter also requested the Secretary to review the situation and to advise the committee whether the Department might feel the need for additional legislation granting the Department power to allocate the vaccine.

The bill on which the administration now has requested action is designed to authorize an appropriation of $28 million to assist the States in providing, for a limited period, Salk vaccine immunizations to children of parents who may not be able to pay for the cost of the vaccine.

Paralleling this bill, the administration has proposed a voluntary system of allocations and priorities to assure that the Salk vaccine, during the initial scarcity period, will be distributed fairly among the several States and will go to the children in those age groups which are most susceptible to the disease.

A great deal has been said already by spokesmen for the administration, interested groups, organizations and Members of Congress, with regard to the adequacy of a voluntary plan.

Many bills have been introduced in Congress to give additional powers to the President for a limited period of time to deal with specific allocation and priority problems arising from the present scarcity of the Salk vaccine.

I have introduced H. R. 6207 for the purpose of raising the question whether permanent legislation is needed granting powers to the Secretary of Health, Education, and Welfare through an amendment of the biologics control law to control, through regulations, in the interest of public health, the distribution and use of biological products.

I have particularly in mind that these additional powers may be needed in all instances where, as in the case of the Salk vaccine, rapid mass applications are attempted of new biological products.

In this connection I further desire to raise a question whether there is continued justification for differentiation in responsibilities of the Federal Government with regard to:

(1) new biological products;
(2) new drugs; and
(3) insulin and certain specified antibiotics.

I want to call to the attention of the departments and agencies of the Federal Government, the State and local governments, the voluntary agencies, the pharmaceutical trade, and the medical and pharmaceutical professions, and last but not least, the American public generally, the new problems created by the rapid mass application of new "wonder" drugs as exemplified by recent experiences with the Salk vaccine.

Therefore, I have directed the committee staff to prepare a series of questions which will focus attention on some of the problems created by the new phenomenon of rapid mass application of new drugs.

The answers to these questions cannot and will not be forthcoming during the few days of hearings that this committee can hold on the two bills now before it. However, the answers to these questions should be found at a reasonably early date.

The best way in my view to secure reasonable answers, including necessary additional Federal legislation, is to conduct an intelligent

discussion of these questions. In order to promote an early start of this discussion, I am making the questions public at this time in advance of the hearings in the hope that all interested groups and individuals will give their careful attention to these questions.

(The questions are as follows:)

A. RESPONSIBILITIES OF FEDERAL GOVERNMENT UNDER PRESENT LAW

1. Under present law, what are the responsibilities of the Federal Government with respect to new drugs as to (*a*) production and safety; (*b*) distribution; and (*c*) application and use?

2. Under present law, what are the responsibilities of the Federal Government with respect to new biological products, as to (*a*) production and safety; (*b*) distribution; and (*c*) application and use?

3. Under present law, what are the responsibilities of the Federal Government with respect to certain new drugs, including insulin, and several specifically enumerated antibiotics, as to (*a*) production and safety; (*b*) distribution; and (*c*) application and use?

4. What accounts for the difference in responsibilities?

5. Is this difference in responsibilities justified?

B. RAPID MASS APPLICATION V. GRADUAL INDIVIDUAL APPLICATION

6. Are there any public policy considerations which distinguish rapid mass application of new drugs from gradual individual application with regard to (*a*) production and safety; (*b*) distribution; and (*c*) application and use?

7. Do these considerations differ according to whether such drugs are primarily preventive or curative?

C. RESPECTIVE RESPONSIBILITIES

8. What are the respective responsibilities (legal and other) in connection with rapid mass applications of new drugs ((*a*) preventive, or (*b*) curative) of—

A. Governmental agencies (Federal, State, and local)
B. Voluntary agencies
C. Manufacturers, wholesalers, retailers, and pharmacists
D. Medical profession (indiyidually and collectively)
E. Others?

9. Are these respective responsibilities the same in the case of rapid mass application and in the case of gradual individual application of new drugs?

10. Are present Federal laws adequate for the discharge of Federal responsibilities in connection with rapid mass application and gradual individual application of new drugs (preventive or curative) with regard to (*a*) production and safety; (*b*) distribution; and (*c*) application and use?

In closing, I want to emphasize again that in spite of the broad scope of the committee's inquiry, there will under no circumstances be any delay in taking up H. R. 6286, which contains the administration's proposed authorization of $28 million to assist the States in providing immunization against poliomyelitis for children whose parents are unable to pay the cost of vaccination.

The bills, H. R. 6286 and H. R. 6207, will be inserted in the record at this point.

(The bills, H. R. 6286 and H. R. 6207 are as follows:)

[H. R. 6286, 84th Cong., 1st sess.]

A BILL To protect the public health by providing for grants to assist States in assuring that no child is deprived of an opportunity for immunization against poliomyelitis because of inability to pay the costs of vaccination, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Poliomyelitis Immunization Assistance Act of 1955".

AUTHORIZATION OF APPROPRIATIONS

SEC. 2. For the purpose of assisting States to assure that no child will be denied immunization against poliomyelitis, during the current shortage of the poliomyelitis vaccine, because of inability to pay for the cost thereof, there is hereby authorized to be appropriated not to exceed $28,000,000, to remain available until December 31, 1956. Sums appropriated pursuant to this section shall be used for making payments to States which have submitted, and had approved by the Secretary of Health, Education, and Welfare, applications for carrying out the purposes of this Act.

ALLOTMENTS TO STATES

SEC. 3. (a) From the sums appropriated pursuant to section 2, the Secretary shall allot to each State which has an application approved pursuant to section 4 an amount equal to 20 per centum of the number of unimmunized children in such State multiplied by the product of (1) the cost of the poliomyelitis vaccine per child and (2) the State's allotment percentage. The amount so computed for each State shall be reduced by the percentage by which such sums appropriated pursuant to section 2 or less than the total of the amounts so computed for all States.

(b) A State's allotment percentage shall be equal to the per capita income of the United States divided by the per capita income of the State. Such percentage shall be determined by the Secretary, in accordance with regulations, on the basis of information furnished by the Department of Commerce; except that the allotment percentage for Hawaii shall be 100 per centum and for Alaska, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Canal Zone shall be equal to the allotment percentage determined above for the one of the forty-eight States which has the lowest per capita income.

STATE APPLICATIONS FOR FUNDS

SEC. 4. The Secretary shall approve the application of any State for payments under this Act if such application—

(a) sets forth a statewide program for use of the poliomyelitis vaccine purchased with funds paid to the State under this Act, which contains reasonable assurance that no child, or, if (and for so long as) any priority groups are established by the Secretary under this Act, no child within such priority group or groups will be denied vaccination against poliomyelitis because of inability to pay the cost thereof: *Provided*, That this shall not prevent a State from providing for the free vaccination against poliomyelitis, without regard to ability to pay, of all unimmunized children, or all such children within any one or more groups determined by the State, but, in such case, the amount paid to such State under this Act with respect to the poliomyelitis vaccine for such children may not exceed the allotment percentage for such State multiplied by the cost of the vaccine for 20 per centum of such children;

(b) provides for administration or supervision of administration of the program included in the application by a single State agency;

(c) provides that the State agency will make such reports, in such form and containing such information, as the Secretary may from time to time reasonably require to carry out his functions under this Act, and comply with such provisions as he may from time to time find necessary to assure the correctness and verification of such reports; and

(d) provides such accounting, budgeting, and other fiscal methods and procedures as are necessary for the proper and efficient administration of the program.

PAYMENTS TO STATES

SEC. 5. The Secretary shall from time to time estimate the amount to be paid to each State under the provisions of this Act for any period, and shall pay such amount to such State, from the allotment available therefor, reduced or increased, as the case may be, by any sum (not previously adjusted under this section) by which he finds that his estimate of the amount to be paid to the State for any prior period under this Act was greater or less than the amount which should have been paid to the State for such prior period under this Act. Such payments shall be made in such installments as the Secretary may determine.

USE OF FUNDS PAID TO STATES

SEC. 6. Funds paid to a State under this Act may be used solely for the purchase, prior to December 31, 1956, of the poliomyelitis vaccine for use in carrying out the program set forth in the application of such State approved pursuant to section 4.

FURNISHING OF VACCINE BY SECRETARY

SEC. 7. At the request of any State the Secretary may use all or any portion of the allotment of such State under this Act for the purchase of the poliomyelitis vaccine, to be furnished to the State in lieu of such State's allotment (or such portion thereof). Vaccine so furnished shall be subject to the same requirements as to use as vaccine purchased from payments to States pursuant to this Act.

PRIORITIES AND ADVISORY COMMITTEE

SEC. 8. Priorities established by the Secretary for purposes of section 4 (a) shall be based on the relative susceptibility of various age groups of children to poliomyelitis. The Secretary is authorized to establish an advisory committee on distribution of the poliomyelitis vaccine to advise and assist him in the establishment of such priorities. Appointed members of such committee who are not otherwise in the employ of the United States, while attending conferences or meetings of the committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at a rate to be fixed by the Secretary but not exceeding $50 per diem, including travel time, and while away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law.

DIVERSION OF FEDERAL FUNDS

SEC. 9. Whenever the Secretary, after reasonable notice and opportunity for hearing to the State agency administering or supervising the administration of the program included in the application of such State approved under section 4, finds that—

(a) such State agency is not complying substantially with the provisions of this Act or the terms and conditions of its approved application; or

(b) any funds paid to such State or supplies of vaccine furnished to it under this Act have been diverted from the purposes for which paid or furnished;

the Secretary shall notify such State agency that no further payments will be made (or no further supplies of vaccine will be furnished) to the State under this Act until he is satisfied that there is no longer any failure to comply or the diversion has been corrected or, if compliance or correction is impossible, until such State agency repays or arranges for the repayment of Federal funds which have been diverted or improperly expended (or for repayment of the cost of the vaccine which has been diverted).

DEFINITIONS

SEC. 10. For purposes of this Act—

(a) The term "Secretary" means the Secretary of Health, Education, and Welfare;

(b) (1) The term "child" means any individual who has not attained the age of twenty years;

(2) The number of children shall be determined by the Secretary as of June 30, 1955, on the basis of the latest information furnished by the Department of Commerce;

(3) The number of unimmunized children means the number of such children, reduced by the extent to which any such child has received the vaccinations against poliomyelitis, determined by the Secretary as of such date or dates as he may select for purposes of this Act;

(c) The term "State" includes Alaska, Hawaii, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Canal Zone, and the District of Columbia;

(d) The cost of the poliomyelitis vaccine shall be determined by the Secretary on the basis of information available to him; and such cost may be determined from time to time or as of a specified date, and may be determined to be a single figure for all States or varied in accordance with actual cost.

[H. R. 6207, 84th Cong., 1st sess.]

A BILL To amend subsections (a) and (b) of section 351 of the Public Health Service Act, as amended

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That subsections (a) and (b) of section 351 of the Public Health Service Act, as amended (42 U. S. C., sec. 262 (a)), are hereby amended to read as follows:

"SEC. 351. (a) No person shall sell, barter, or exchange, or offer for sale, barter, or exchange in the District of Columbia, or send, carry, or bring for sale, barter, or exchange from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession, any virus, theraputic serum, toxin, antitoxin, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man, unless (1) such virus, serum, toxin, antitoxin, or other product has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Administrator as hereinafter authorized, to propagate or manufacture, and prepare such virus, serum, toxin, antitoxin, or other product for sale in the District of Columbia, or for sending, bringing, or carrying from place to place aforesaid; (2) each package of such virus, serum, toxin, antitoxin, or other product is plainly marked with the proper name of the article contained therein, the name, address, and license number of the manufacturer, and the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results; and (3) in the case of any such virus, serum, toxin, antitoxin, or other product, the distribution or use of which has been found by the Secretary of Health, Education, and Welfare to require supervision and control in the interest of protecting and preserving the health of the American people, such sale, barter, or exchange, or offer for sale, barter, or exchange, or sending, carrying, or bringing for sale, barter, or exchange, is in compliance with such orders or regulations governing the distribution or use as the Secretary shall prescribe as necessary or appropriate to protect and preserve the health of the American people. The suspension or revocation of any license shall not prevent the sale, barter, or exchange of any virus, serum, toxin, antitoxin, or other product aforesaid which has been sold and delivered by the licensee prior to such suspension or revocation, unless the owner or custodian of such virus, serum, toxin, antitoxin, or other product aforesaid has been notified by the Administrator not to sell, barter, or exchange the same.

"(b) No person shall falsely label or mark any package or container of any virus, serum, toxin, antitoxin, or other product aforesaid; nor alter any label or mark on any package or container of any virus, serum, toxin, antitoxin, or other product aforesaid so as to falsify such label or mark. In the case of any virus, serum, toxin, antitoxin, or other product subject to subsection (a) (3) of this section no person shall resell, barter, exchange, or use, or offer for resale, barter, exchange, or use, such virus, serum, toxin, antitoxin or other product unless such resale barter, exchange, or use, or offer for resale, barter, exchange, or use, is in compliance with such orders or regulations governing the distribution or use as the Secretary of Health, Education, and Welfare shall prescribe as necessary or appropriate to protect and preserve the health of the American people."

The CHAIRMAN. We open the hearings today with Mr. Roswell Perkins, the Assistant Secretary, who on this occasion, I believe, is speaking for the Secretary; is that correct?

STATEMENT OF HON. OVETA CULP HOBBY, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, PRESENTED BY ROSWELL B. PERKINS, ASSISTANT SECRETARY; DR. LEONARD A. SCHEELE, SURGEON GENERAL; DR. CHESTER S. KEEFER, SPECIAL ASSISTANT FOR HEALTH AND MEDICAL AFFAIRS; DR. W. H. SEBRELL, JR., DIRECTOR, NATIONAL INSTITUTES OF HEALTH; BRADSHAW MINTENER, ASSISTANT SECRETARY; PARKE BANTA, GENERAL COUNSEL; AND GEORGE LARRICK, COMMISSIONER, FOOD AND DRUG ADMINISTRATION

Mr. PERKINS. That is correct. Secretary Hobby is extremely sorry and sends her regrets to the committee that she was unable to be here today.

Mr. DOLLINGER. I thought the Secretary was going to be here this morning. So much confusion has been raised in the mind of the public that I thought the committee would get the opportunity to speak to the Secretary and get information from her after she had given her statement.

Is the Secretary going to be here at some time in the future?

The CHAIRMAN. That is entirely possible.

Mr. DOLLINGER. I would like to know, Mr. Chairman, because if she is not I do not think this committee should listen to the Assistant Secretary. It is her statement and I think we have the right to question her.

The CHAIRMAN. May the Chair state that I do not think this is giving out any sort of personal secret, but Mrs. Hobby was called to Texas because of the illness of her husband. Mrs. Hobby is not in town. She called long distance last night to explain why she was not able to be here and I thought that would be entirely understood at this time. Her prepared statement will be presented by the Assistant Secretary.

Mr. DOLLINGER. May I make my point clear?

The reason I raised the point is that in the past there have been many hearings where she had not appeared. I was wondering whether she was trying to avoid questioning by the committees of Congress and that is what I wanted the record to indicate.

The CHAIRMAN. The gentleman has certainly the right to raise that question.

In the opinion of the Chair, there was not any plan on the part of the Secretary not to be present for this hearing this morning except for personal circumstances. The chairman talked to her personally last week and she was interested in this hearing and indicated at the time that she expected to be present for the hearing.

I make that explanation because I believe that that is the true situation. We will be continuing this discussion over into another week and we may have the Secretary, if her personal situation permits, appear at that time before the committee.

However, I am sure Mr. Perkins is prepared to present her viewpoint and to answer questions by the committee.

Mr. FRIEDEL. Mr. Chairman, I would just like to ask one question.

Would Mr. Perkins be able to answer questions with authority or reservations?

The CHAIRMAN. Mr. Perkins would have to answer that for himself. I assume that since he holds the position of Assistant Secretary, he will be able to answer questions with authority.

Mr. HARRIS. Mr. Chairman, may I make this suggestion in an effort to reach an understanding.

If there are any questions here this morning which members feel should be answered directly by the Secretary, I am wondering if some convenient date cannot be agreed on in the near future on which Mrs. Hobby could be here for that purpose. I believe that it could be arranged.

The CHAIRMAN. I feel certain it could if questions arise on which Mr. Perkins does not feel that he should speak for the Secretary. I think that can be arranged and the gentleman has made a helpful suggestion, as usual.

Mr. Klein?

Mr. KLEIN. Mr. Chairman, I agree that you have a point that if the Assistant Secretary feels that there are certain questions that Mrs. Hobby only can answer, and why do we not also have the reservation that if we feel there are certain questions only she can answer, we will hold them for her?

The CHAIRMAN. I think that is a good suggestion and, with those understandings, we shall proceed now.

Mr. PERKINS. Mr. Chairman and members of the committee, I am pleased to appear before you today in support of identical bills H. R. 6286 and H. R. 6287, which would implement one of the key recommendations in our May 16 report to the President on distribution of Salk vaccine. Copies of that report were made public on the same day.

BACKGROUND

Before proceeding to an analysis of the provisions of the bill itself, I believe that a brief review of the background of policy and program development relating to this particular proposal will be helpful.

PRINCIPLES UNDERLYING PROPOSED PROGRAM

As we stated in our report to the President, the principles that guided us in our study of the situation and in our actions to date are:

1. Safety of the vaccine must be the paramount consideration, and the questions relating to safety in quantity production must be determined by the best scientific advice, uninfluenced by any other factors.
2. The vaccine must be distributed on an equitable basis among the States and among individuals within the States.
3. Children should be able to receive the vaccine regardless of the ability of their parents to pay.
4. Any distribution system adopted must be as practical, fast, and effective as is possible while still meeting the foregoing principles.

PROPOSED DISTRIBUTION PLAN

On the basis of these principles, we presented to the President a proposed plan for an equitable and effective distribution flow, commencing with the manufacture and proceeding down to the individual child within the priority age group.

This plan is designed to take effect immediately upon completion of the free immunization program still being conducted by the National Foundation for Infantile Paralysis.

It should be kept in mind that this program, the NFIP program, has been in progress ever since April 12 and that all vaccine being currently produced and released is being devoted to the NFIP program.

The highlights of the distribution plan are contained in the following recommendations included in the report to the President and approved by him:

Recommendation No. 2.—National Foundation for Infantile Paralysis free immunization program: That all current distribution be directed toward fulfillment, at the earliest possible date, of NFIP contracts and the free immunization program for first and second graders.

Recommendation No. 3.—Priorities: That, in accordance with the recommendations of the National Advisory Committee on Poliomyelitis Vaccine, the vaccine should be administered for the time being only to children of the most susceptible age group, 5 to 9, inclusive.

Further priorities should be announced from time to time on the basis of recommendations of the National Advisory Committee.

Recommendation No. 4.—Departmental responsibility: That the Secretary of Health, Education, and Welfare direct on a national level the division among the States of the entire output of Salk vaccine, as pledged by the manufacturers.

Recommendation No. 5.—Plan of allocation among the States: That the supplies of vaccine be allocated to each State on the basis of its population of children within the 5-to-9 age group until all children of that age group have been vaccinated. The Secretary will receive continuing reports from the manufacturers as to their total output and deliveries, and will keep the individual manufacturers advised of the quantities of vaccine they should ship to each State to assure fair allocation.

Recommendation No. 6.—State responsibility: That each State, through an appropriate single agency to be designated by the governor of the State, direct the distribution of the vaccine within the State. The State agency should advise the Secretary of Health, Education, and Welfare on the desired shipment of the State's allocation; for example, that portion which should be distributed through normal drug distribution channels and that portion which should be shipped to public agencies.

Recommendation No. 7.—Enforcement of Food, Drug, and Cosmetic Act and State laws: That, in order to give special attention to vigorous enforcement of those portions of the food and drug law prohibiting sales of the vaccine outside authorized channels for prescription drugs, additional funds be requested for Food and Drug Administration of the Department of Health, Education, and Welfare.

It is further recommended that State and local officials give special emphasis to the enforcement of applicable State laws relating to prescription drugs.

Recommendation No. 8.—Adherence to priority plan by physicians; recordkeeping: That, with the cooperation of the medical profession pledged to insure the success of a voluntary control plan, medical organizations take all appropriate steps to assure that:

(a) physicians will adminster vaccinations only to, and issue prescriptions only for, children within the priority age groups;

(b) physicians will, in accordance with the recommendations of the National Advisory Committee on Poliomyelitis Vaccine, keep a record of the name of each child receiving a vaccination, the age of the child, date of vaccination, site of vaccination (place on body), name of the manufacturer of the vaccine used and the lot number.

Recommendation No. 9—Recordkeeping by distributors: That manufacturers, pharmaceutical organizations, wholesale and retail drug organizations and States and other public agencies, whose cooperation to make a voluntary control plan work has also been pledged, take necessary steps to assure that every distributor of the vaccine keep a record of the name of the manufacturer, the lot number, and the customer receiving the vaccine he handles.

Under this plan, as indicated by recommendation No. 6, each State would assume responsibility for supervising the flow of vaccine within the State.

The State health officer might, for example, indicate to the Department of Health, Education, and Welfare that his State wanted 70 percent of the State's allocation of vaccine to be shipped into the State through normal distribution channels, with the remaining 30 percent to be shipped to designated public agencies within the State. The latter portion of the vaccine would be presumably purchased with public funds.

It is apparent that in order to assure free vaccination of children who could not otherwise afford it, the States will need additional funds. Many steps have been taken by State legislatures, local public bodies, political organizations, groups of doctors, and other groups of citizens, to assure free vaccination of such children.

The President has expressed his desire that no child will be denied immunization by reason of financial inability of his parents to pay. It is out of these basic considerations that recommendation No. 10 of our report to the President and the legislation before this committee today arises.

THE PROPOSED GRANT PROGRAM

This recommendation reads as follows:

Recommendation No. 10—Federal funds for grants to States: That legislation which has been prepared by this Department be submitted to the Congress to make Federal funds available to the States for the purchase of vaccine, or, in lieu of funds, the vaccine itself.

These funds must be sufficient to pay the cost of vaccine for children through age 19 in low-income families. The funds would be used after the NFIP free immunization program has been completed and until December 31, 1956. These funds would be paid to States upon assurance by the State that no child within the priority age groups would be denied vaccination by reason of the cost.

Draft legislation to implement this recommendation No. 10 was transmitted to the Congress on May 16 and introduced the following day.

The remainder of our testimony will be directed toward the provisions of this legislation. However, to summarize, our report to the President incorporates a program which, in our opinion, will:

1. Apply to the distribution of vaccine after the material requirements of the NFIP program have been met for the country as a whole;
2. Assure equitable distribution of available vaccine among the several States and Territories;
3. Give first priority to children in the age categories most in need of protection;
4. Place responsibility for establishing national priority and allocation policies in the Department of Health, Education, and Welfare;
5. Place responsibility for intrastate distribution in a single State agency designated by the governor for this purpose;
6. Provide for joint Federal-State action in assuring that the cost of vaccination will not be a barrier to its equitable distribution to children most in need of protection.

PROVISIONS OF THE BILL

The objective of the bill, as indicated in the title, is—

> to assist the States in assuring that no child is deprived of an opportunity for immunization against poliomyelitis because of inability to pay the costs of vaccination * * *.

Although this objective reflects our concern with protection of children in low-income families, there is nothing in the bill to require or suggest that a separate program be established for such children. Nor is there any provision defining or requiring any "means test" to determine the ability of a family to pay for the vaccination. The States are left with complete discretion on this matter.

The bill simply requires, as a grant condition, that a State's application must set forth a statewide program for use of the vaccine purchased with the federally granted funds, and that this program must include reasonable assurance that no child will be denied vaccination because of inability to pay the costs. The methods by which such assurance will be fulfilled will vary among the several States.

In all States there are well-established public-health policies and procedures for the provision of various types of immunizations without cost, or at minimal cost, in local health departments, clinics, schools, or private physicians' offices.

Some State and local government and some voluntary organizations have already made available funds to help defray the costs of poliomyelitis vaccinations. In other States, arrangements will be developed specifically for this program which will provide vaccination for all children in the priority age groups, without regard to ability to pay.

The bill includes a statutory formula for determining the amount of funds to which each State with an approved application will be entitled. This formula provides that each State shall receive an amount equal to 20 percent of the unimmunized children in the State, multiplied by the cost of the vaccine per child and by the State's allotment percentage.

This allotment percentage is determined by dividing the per capita income of the United States by the per capita income of the State. Special allotment percentages are established in the legislation for the territories and possessions.

The effect of this formula is to provide funds sufficient to purchase vaccine for a higher percentage of unvaccinated children in the lower income States than in the higher income States.

For example, sufficient funds would be made available to purchase vaccine for 41 percent of the unvaccinated children in the lowest income State and for 14.8 percent of the unvaccinated children in the highest income State.

On a national basis the formula would provide sufficient Federal funds to purchase vaccine for approximately 22 percent of the unvaccinated children, or a total of approximately 13,350,000 children. Of this number, approximately 11,500,000 would receive 3 injections. The remainder would be first- and second-grade children receiving their third injection, having received the first two through the National Foundation for Infantile Paralysis.

Attached as a supplement to this statement is a tabulation which shows the estimated allocation of funds to each State, computed under the statutory formula.

In order to become entitled to receive its allocation, each State would submit an application for the approval of the Secretary. This application would contain the assurance, which I mentioned earlier, that no child would be denied the vaccination because of inability to pay the cost.

In addition, it would provide for:

1. Administration or supervision of the program by a single State agency;

2. Such reports by the State agency as the Secretary may reasonably require; and

3. Such accounting and fiscal methods as are necessary for proper and efficient administration of the program.

Payments from a State's allocation would be made periodically on the basis of estimates of the amount needed for the program in that State for a future period. These payments would be adjusted from time to time to correct for overpayments or underpayments previously made.

At the request of a State, the Secretary would also be authorized to provide vaccine to a State in lieu of a cash payment and to use the funds in a State's allocation to purchase vaccine for that purpose.

There is no requirement in the bill for "matching funds" to be supplied by the States and localities. Although it is expected that State and local funds will be provided to supplement Federal grant funds, a statutory matching requirement was omitted for two reasons:

First, grant funds may be used only for the purchase of vaccine; therefore States, communities, or voluntary groups will be responsible for providing or arranging for the professional services required for injections.

Second, if there should be any lag in the provision of matching funds because of delays in State or local appropriations procedures, a statutory matching requirement might impede inauguration of any program of free vaccination for children from low-income families.

In administering this program, the Secretary would be authorized to establish priority age groups within the total child population. In such a case, the assurances required of the State in its application would have to apply only to the priority age groups established until

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sufficient vaccine becomes available to permit enlarging the priority groups or eliminating them altogether. These priority age groups would be established on advice of an expert advisory committee on distribution of the poliomyelitis vaccine. I should note that that committee has already been established, the National Advisory Committee on Poliomyelitis, which has been operating for several weeks.

If a State wishes, its program may provide for free vaccination for all children or for all children in any group or groups selected by the State. In such a case, however, the amount paid under these bills could not exceed the State's allotment as determined by the statutory formula.

The program of financial assistance envisioned by this legislation would extend to all of the 48 States, the District of Columbia, Alaska, Hawaii, Puerto Rice, the Virgin Islands, American Samoa, Guam, and the Canal Zone.

In computing the number of unvaccinated children, we would exclude from the total child population under 20 years of age the approximately 423,000 children who were vaccinated in the National Foundation for Infantile Paralysis field trial last year, as well as the approximately 8,800,000 children whom we estimate are eligible for vaccination in the current NFIP program for first- and second-grade schoolchildren. The latter group, however, will be included for purposes of the third injection, which is not scheduled to be provided under the NFIP program.

CONCLUSION

In conclusion, Mr. Chairman, the proposed legislation will provide:

1. Necessary financial assistance until December 31, 1956, to enable States with their varying fiscal resources to carry out a program of poliomyelitis vaccination among children in the highest priority age groups; and

2. Assurances that no child in the United States during this period will be denied an opportunity to be vaccinated because of inability to pay.

We believe that this program, operating within the framework of our traditional Federal-State relationships, will result in effective protection against infantile paralysis for the children of the Nation.

Mr. Chairman, I should note that we are preparing several clarifying or technical amendments to the bill and would be happy to submit them to the committee or its staff at its pleasure.

I have also, Mr. Chairman, a report on the second bill, second item of legislation under consideration today, H. R. 6207. I regret that we do not have mimeographed copies of that report but if it is the chairman's wish, I would be glad to read it into the record.

The CHAIRMAN. Very well, Mr. Perkins, I believe you may read it into the record since we do not have copies.

Mr. PERKINS (reading):

DEAR MR. CHAIRMAN: This letter is in response to your request of May 16, 1955, for a report on H. R. 6207, a bill to amend subsections (a) and (b) of section 351 of the Public Health Service Act, as amended. This bill would amend section 351 of the Public Health Service Act by adding to subsection (a) provisions authorizing the Secretary of Health, Education, and Welfare:

1. To find whether the distribution or use of any biologic product requires supervision and control in the interests of protecting and preserving the health of the American people.

2. Upon such finding, to issue such orders or regulations as necessary or appropriate to protect and preserve the health of the American people. These orders and regulations would be applicable both to the sale or offer for sale of a biological product, apparently only in the District of Columbia and also to the sending, carrying, or bringing of the product for sale between States or into a foreign country or into the United States or a possession from a foreign country. The bill would also admit to subsection (b) of section 351 provisions that would prohibit any person from selling any biological product or from offering it for sale without compliance with the orders or regulations prescribed by the Secretary.

The bill is not limited to any particular emergency problem of distribution and use of a new biologic, such as poliomyelitis vaccine; rather, it would extend to the Secretary's discretionary authority to establish Federal control over the distribution and use of "any virus, serum, toxin or antitoxin, or other product." Moreover, in exercising this discretion, the Secretary would need only make a finding that the distribution or use of the product requires "supervision and control in the interest of protecting and preserving the health of the American people."

The most basic question of public policy raised by the provisions of H. R. 6207 is whether the responsibility of the Federal Government with respect to biological products should be extended beyond the determination of potency and safety to embrace some additional responsibility for the distribution and use of such products "in the interest of protecting and preserving the health of the American people." A corollary question is should any such additional responsibility be based on the statutory powers to regulate and control distribution and use. We are not prepared at this time to offer any definitive conclusions as to the possible need for revision of the present statutory authority in order to deal effectively with any situation which might conceivably arise in the future. We have already initiated studies within our department to determine whether the experience gained from the production, testing, and distribution of poliomyelitis vaccine indicates a need for revision of our present statutory authority. Any legislative recommendations arising from this review will, of course, be submitted to the Congress at the earliest practicable date.

With respect to the current problem of equitable distribution of poliomyelitis vaccine, we have concluded, as included in our May 16, 1955, report to the President, that additional statutory authority is not necessary. If consideration should be given to legislation authorizing further Federal controls over the distribution and use of biological products, particular attention should be given to a clear definition of these powers and the circumstances under which they may be exercised. The lack of a fairly specific standard for action by the Secretary is, in our opinion, a serious defect of the bill. The distribution and use of a new biological product usually involves a number of interested parties other than the Federal Government and the manufacturer. In the case of a widely sought product such as polio vaccine, State and local governments, voluntary agencies, the medical profession, and individual citizens are all interested parties. Such interested groups are entitled to more definite assurances in the legislation of the circumstances under which it would be proper for the Secretary to assert control over the distribution and use of a biological product. All but a very few of the 1,100 licensed biological products today are used only on prescription by a physician as needed for an individual patient. Each product is manufactured under minimum Federal standards and the available supply is easily adjusted by the manufacturer to fit the continuing demand for the product. When so used, there is no need of Government control of the distribution and use of the product and the language of any amendment to the Public Health Service Act should make this clear.

From the standpoint of biologic manufacturers, the lack of clear statutory standards relating to controls over distribution and use might have serious consequences. The uncertainty which this legislation might create with respect to the policies governing distribution of most biologics could have the effect of discouraging new biologic development in which substantial investment capital is involved and/or increasing the cost of biologics to the ultimate user.

In summary, we are not prepared at this time to offer any general recommendations as to the need for new or revised statutory authority relating to biological products and we believe that H. R. 6207 as presently worded would confer such broad discretionary authority on the Secretary as to raise serious questions of policy and administration. We would, therefore, recommend that

the bill not be enacted and that final consideration of the proposal be deferred pending further analysis of need for statutory revision.

The Bureau of the Budget advises that it perceives no objection to the submission of this report to your committee.

The CHAIRMAN. Thank you, Mr. Perkins.

I know that every member of this committee has a great many questions in mind because every Member of the House of Representatives has had letters from constituents, and this committee in particular has had a great many questions presented to it by constituents and by other Members of the House who feel that this particular committee has a responsibility in this field, being the legislative committee having to do with health legislation.

I simply want to ask one or two questions and then will permit other members of the committee to do so.

The formula of allocation, as I understand it, operates as follows: 20 percent of the unimmunized population between the ages of 1 and 20, multiplied by the product of (1) the cost of the vaccine and (2) the State's allotment percentage, gives us the amount that would be allocated to each State. And the allotment percentage is arrived at by dividing the national per capita income by the State's per capita income.

Now, before noticing your table, I figured an example: A State reports that 20 percent of the number of unimmunized persons between those ages is 50,000, and I figured the cost of the vaccine at $6. I notice in the table there is a $2.33 figure that I want to ask another question about.

I assume, for the sake of working out the formula, that the per capita income of the entire United States is $3,600 and that in this particular State is is $1,800, which gives a figure of 2. That gives that State an allotment percentage of 2 multiplied by 6, multiplied by 50,000, which was 20 percent of the unimmunized population, and that such a State—would get $600,000, using those figures; that is the way the formula works, is it not?

Mr. PERKINS. That is correct.

The CHAIRMAN. Assuming those figures, that would be the allocation of funds to that particular State?

Mr. PERKINS. Yes, sir.

The CHAIRMAN. I have another question. I was interested in reading the table here. "Estimated cost of vaccine for unvaccinated children under Federal aid program at $2.33 for 3 cubic centimeters."

The question that came to my mind is how that figure has been reached, the figure of $2.33 for 3 c. c.

Mr. PERKINS. That figure was a figure which it is our understanding the manufacturers would tentatively plan to charge to public agencies buying in large quantities.

The CHAIRMAN. Mr. Perkins, is that the amount or is there a different amount charged by the manufacturers to the foundation for its program?

Mr. PERKINS. The foundation figure is substantially less than that. The foundation, as you know, in effect underwrote the initial operations of the manufacturers by signing contracts for a substantial output irrespective of the success of the trials; that is my understanding of the arrangement. On that basis, in effect putting up risk capital

and not knowing the ultimate final cost, the foundation was able to obtain a price of, it is my understanding, $1 or $1.100 for the 3 c. c.

The CHAIRMAN. $1.90?

Mr. PERKINS. $1 or $1.10.

The CHAIRMAN. For 3 c. c.?

Mr. PERKINS. For 3 c. c.

The CHAIRMAN. Then this figure, as you understand it, for $2.33 for 3 c. c. is the amount for which the manufacturers have agreed to furnish this vaccine to public agencies that are carrying on the program?

Mr. PERKINS. Yes. It would be hard to say "agreed to," because I do not think there are any agreements; but it is a tentative plan, tentatively quoted price.

The CHAIRMAN. One other question, and I am not going to ask a great many questions at this point.

The administration of this grant-in-aid program, will that be under the Children's Bureau or the Public Health Service?

Mr. PERKINS. The discretion would be in the Secretary to delegate her powers of administration to any agency within the Department. It would be a matter to be determined by her. We have naturally given it considerable thought, but have come to no definite conclusions.

In any event, there would have to be, it would seem, close coordination between several units of the Department. The Public Health grants programs under the Bureau of State Services of the Public Health Service, which administers the assistance to States general, would have a close interest in it, and any other units of the Public Health Service concerned with the distribution program itself and the allocation plans, would have a direct and close interest.

The Children's Bureau would obviously have a close and direct interest and also the special adviser to the Secretary for Health and Medical Affairs, Dr. Keefer. Thus, under any plan or ultimate delegation of responsibility, we would hope to gear in those units as closely as possible.

The CHAIRMAN. One further question, Mr. Perkins, at this point.

The contracts entered into by the foundation with the manufacturers of the vaccine, were entered into on an entirely private basis? They are simply agreements between the manufacturers and the foundation?

Mr. PERKINS. That is correct.

The CHAIRMAN. In that particular connection, the Department or the Public Health Service had no jurisdiction whatsoever over that contract?

Mr. PERKINS. You are correct, sir.

The CHAIRMAN. I will pass up further questions at this point to permit other committee members to ask questions of Mr. Perkins.

Mr. Wolverton?

Mr. WOLVERTON. No questions.

The CHAIRMAN. Mr. Harris?

Mr. HARRIS. Mr. Secretary, have you been close to this problem, participating in it since the announcement was made in the early part of April?

Mr. PERKINS. Yes, sir; I think I would say that, yes.

Mr. HARRIS. Have you participated with the other officials of the Department in the developments over these weeks?

Mr. PERKINS. Yes, sir.

Mr. HARRIS. What authority, present authority, under the law does the Department have over control of the vaccine?

Mr. PERKINS. The first point at which the Department has statutory responsibility is with respect to the licensing of the manufacturers and the approval of the product under the biologics control provisions of the Public Health Service Act. Those provisions relate solely to the safety and potency of the vaccine.

There are no provisions giving the Department statutory authority to control on any mandatory basis the allocation and distribution of the vaccine.

So, in brief, we have statutory powers with respect to licensing, safety and potency, but no statutory powers giving compulsory controls over the allocation and distribution of the product.

Mr. HARRIS. How many manufacturers have you licensed?

Mr. PERKINS. Six, sir.

Mr. HARRIS. Will you name them for the record?

Mr. PERKINS. They are Parke-Davis & Co., Eli Lilly & Co., Wyeth Laboratories, Pitman-Moore Co., Cutter Laboratories, and Sharp & Dohme, Inc., those six. Those are not their full corporate titles necessarily.

Mr. HARRIS. After you licensed the manufacturers, then do you have any further responsibility and authority with reference to that manufacturers' distribution of this vaccine?

Mr. PERKINS. Yes, sir. It is our construction of the Biologics Control Act that it gives the Public Health Service the power to test, to continue to test, the biologics which are produced by these manufacturers and to exercise certain controls over their release.

Mr. HARRIS. Then, under that authority, you approved the vaccination of children in the United States back in April, a few weeks ago?

Mr. PERKINS. In effect, that is true. The only statutory act was, of course, to license the manufacturers to produce the product.

Mr. HARRIS. Then as a result of some unfortunate cases you stopped the program entirely?

Mr. PERKINS. I should ask the Surgeon General to answer that question.

Mr. HARRIS. Well, we have seen the newspapers, Mr. Secretary, from day to day and I think that is the reason the people in the country are so confused about this whole thing. You are on one day and off the next.

Mr. PERKINS. I would like to clarify what you mean by stopping the program entirely.

Mr. HARRIS. Let me make it a little clearer, then.

There was a program to vaccinate children in certain age groups throughout the United States?

Mr. PERKINS. Yes, sir.

Mr. HARRIS. That program proceeded and in certain areas those children were vaccinated?

Mr. PERKINS. Yes, sir.

Mr. HARRIS. In certain other areas, they had not reached them?

Mr. PERKINS. Yes, sir.

Mr. HARRIS. When the unfortunate experiences that occurred in various places, particularly the west coast and in the Rocky Mountain area, developed, you stopped the program and at that particular time

the other children who had not received the vaccine had their vaccinations suspended, is that true?

Mr. PERKINS. Not quite, sir. The actual events were, as recited in the report to the President, that on April 27 the Surgeon General of the Public Health Service, in response to reports of six cases of poliomyelitis among children who had been vaccinated with material from Cutter Laboratories of Berkeley, Calif., instructed that manufacturer to withdraw all of its vaccine from distribution.

On the same day, two scientists were dispatched from the National Institutes of Health in Bethesda to Berkeley, Calif., to conduct an on-the-scene study of the manufacture and testing of the Cutter product.

The other event which I think pertains to your question is that on May 8 the Surgeon General recommended that all poliomyelitis vaccine programs be temporarily suspended pending a reappraisal of all production procedures and testing methods. The point I wish to make clear is that the program was not stopped in the sense of exercising any kind of control or withdrawal or mandatory cessation of the program. It was a recommendation by the Surgeon General.

It is my understanding that several States continued to vaccinate; is that correct, Dr. Keefer?

Dr. KEEFER. Yes, that is correct.

Mr. PERKINS. So that I did want to qualify and make accurate my answer to your question as to the stopping of the program.

Mr. HARRIS. But the result was that it was temporarily suspended in many areas?

Mr. PERKINS. In many areas following the recommendation of the Surgeon General, the program was temporarily suspended.

Mr. HARRIS. Then you have been conducting surveys and issuing statements to the press almost daily since that time?

Mr. PERKINS. That is in effect true. The Public Health Service announced a plan of reappraisal on the May 8 date that I have referred to already; that reappraisal process has been conducted continuously since then, involving a visitation to the plants of each of the manufacturers. It has culminated yesterday and today in a pooling of the information obtained as a result of this reappraisal process.

Mr. HARRIS. Well, I think it is a highly important matter to reapppraise and I think it is most important to the American people who are so concerned about their children that everything be undertaken that is possible in order to provide a safe program.

What many people are disturbed about, however, is what is going to happen to their children. No later than this morning the headlines of the newspaper said, "Most of all the Salk vaccine is safe."

Well, the American people are not going to get too much comfort from that because when you announce that most of it is safe, who knows whether their child is going to be hit with that part that is not safe?

Mr. PERKINS Well, in answer to that point, I would like to emphasize for the committee's benefit the policy that the Secretary has followed throughout this entire period. She has made it eminently clear to Dr. Scheele that, so far as she was concerned, the administration and the Department were concerned, by far and away the most important issue here was safety, and that no pains must be spared to assure the safety of the vaccine; and that the widest margin of safety was not too much.

It is within that framework that Dr. Scheele has been operating and has been given the time to continue with it, with this reappraisal.

It is our opinion that nothing must interfere with the work of the scientists in completing their reappraisal process.

Mr. HARRIS. I thoroughly agree with that statement; on the other hand, I cannot help but feel that there might be some feeling with regard to some of the reports we see that there has been entirely too much of some type of publicity and show in this matter instead of trying to proceed in order to work it out so that it will not create such a feeling among the American people. That is the thing that disturbs many people and I cannot help feeling that some of these reports are doing that.

That is all, Mr. Chairman.

The CHAIRMAN. Mr. Wolverton?

Mr. WOLVERTON. Mr. Perkins, it would seem that whatever uncertainty that has existed was due to the fact that these six children in California developed poliomyelitis after having received the vaccine.

In the investigation that was made, was it determined whether the vaccine that they had received was the direct cause of their condition or was there any uncertainty about whether the type of vaccine that was given to them was the cause of it?

Just what did the investigation develop with respect either to the efficiency or deficiency of the vaccine that was given to those children?

Mr. PERKINS. I would like to have Dr. Scheele answer that question since it is in the scientific and technical area. I do know that in his recent statement he said that there was sufficient association so that re regarded that as being some "presumptive evidence." I think it is important that Dr. Scheele provide you the most up-to-date answer to that question.

Mr. WOLVERTON. Did it develop, if you are able to answer the question, that there was a deficiency in the formula of Dr. Salk or was it a deficiency or improper manufacture of the formula?

Mr. PERKINS. I respectfully would like to defer that question until Dr. Scheele returns, unless Dr. Keefer would like to answer.

Mr. WOLVERTON. I have 2 or 3 questions along that line and I will wait for Dr. Scheele.

The CHARMAN. May the Chair state that Dr. Scheele notified the chairman before the hearings opened that a very important telephone call concerning this very subject we are dealing with might come up, and he asked to be excused. He will be back rather shortly.

Do you have another question, Mr. Wolverton?

Mr. WOLVERTON. No, I will wait until later.

The CHAIRMAN. Mr. Klein?

Mr. KLEIN. Mr. Secretary, I have a few questions along the line that Mr. Harris has brought out. It is, of course a fact that this is one of the most important matters in the country today and I might say to my friends on the committee that my wife rarely tells me what to do, legislatively, at any rate, but I got a terrible going over last night when I was home and she warned me not to come home unless I got some of these points cleared up.

We have small children, and that is the feeling of all parents at this time. I am very much alarmed. Less than 70 percent of the people

in New York City have availed themselves of the right to obtain this vaccine since it was announced early in April, and I have felt that I think rightly so that this was the greatest discovery of the century.

All the parents of small children rejoiced because they would not have to worry about whether their children would contract this dread disease, and here in a period of perhaps 4 weeks we find that over 30 percent of the people who can get it have refused to let their children get it.

I do not know whether it is your Department that has given out these statements and whether it is inefficiency or negligence, but I think the country has a right to find out.

I would like to ask you some questions in connection with the licensing of manufacturers of the vaccine. As I understand it, you said there were six companies licensed by the Department for the manufacture of the vaccine?

Mr. PERKINS. That is correct.

Mr. KLEIN. Were these companies associated with the preparation or manufacture of the vaccine during the trials that took place since last year?

Mr. PERKINS. Were those companies?

Mr. KLEIN. Yes.

Mr. PERKINS. I will read you an excerpt from the report that may help to answer this.

> There are at present 6 licensed manufacturers of Salk vaccine, the product of 1 of which has been recalled. These were the only companies that the NFIP could interest in entering the field to produce vaccine for use in the large-scale field trial of the vaccine in 1954. Only two of the manufacturers produced quantities early enough and in sufficient volume to be actually used in the field trials.
>
> The expense of tooling up for the production of such large quantities of Salk vaccine was guaranteed in part by NFIP. All six manufacturers also contributed substantial risk capital for the development of plant capacity. Inasmuch as the outcome of the field investigation during 1954 could not be predicted, there was little inducement for other manufacturers to engage in producing the vaccine and no others applied for licenses.

Mr. KLEIN. Was the Cutter Laboratory one of the companies which took part in the field trials during that period?

Dr. SCHEELE. Mr. Klein, the Cutter Laboratory did produce three production lots of vaccine for the trial. Those lots were not, however, used in the field trial because they came along somewhat late and they were small lots. It was decided for purposes of assuring the greatest possible uniformity to use the Parke-Davis and the Lilly lots for the field trial.

But these three production lots which were produced in 1954 by Cutter were intended for the field trial and they all passed the checks of the Cutter Laboratories, Dr. Salk, and the National Institutes of Health.

Mr. HALE. I could not hear that last part.

Dr. SCHEELE. They all passed the tests by the people that made them, Cutter Laboratories, by Dr. Salk and by the National Institutes of Health Laboratory on Biologics Control, but they were not used in the field trial.

Mr. KLEIN. But they were examined and I suppose put to the same tests as the others?

Dr. SCHEELE. That is correct.

Mr. KLEIN. What procedure is followed by the Department in determining who should be licensed to manufacture these vaccines or what procedure did you use in this specific case?

Mr. PERKINS. I will start the answer off by saying that under the statute the licensing is executed by the Secretary upon the recommendation of the Surgeon General.

So far as the Secretary's participation is concerned, the question of licensing was discussed with her by the Surgeon General in advance of April 12. She was fully briefed as to the recommendations that would be made by the Surgeon General if the Francis report turned out to be favorable.

Now, as to going into the background of the Surgeon General's own recommendation to her, I will ask Dr. Scheele to answer the question.

Mr. KLEIN. That may be but I want to ask you, and that is why I wanted Mrs. Hobby to be here.

The recommendations are made by the Surgeon General; that is correct, is it not?

Mr. PERKINS. Yes, sir.

Mr. KLEIN. But the licensing is done by your Department?

Mr. PERKINS. Each license is signed by her.

Mr. KLEIN. I have heard charges made and they are fairly current in Washington, and I do not want to give too much publicity to them at this time because I think this whole program has been characterized with too much publicity, but the story that I heard is that a very, very prominent politician from California brought pressure on Mrs. Hobby, the Secretary of the Department, with regard to licensing the Cutter Laboratories and I would like you to tell me, if you can, and if you cannot I think she ought to come back and tell us.

Mr. PERKINS. I am sure I would know of it if there were any foundation whatsoever to the rumor. I can say categorically that, so far as any information that is available to me, it is absolutely false. The sole information that she had as to the basis for the licensing of these manufacturers came from the Surgeon General.

A summary of the basis for the licensing is set forth in the report to the President which is over her signature and, if the committee would like, I will read the bases on which the licensing was made.

Mr. KLEIN. I just wanted you to categorically respond to this because my information comes from a very reputable source, in my opinion. I am certain the Secretary of your Department is just as patriotic and just as anxious to get a good program inaugurated in this country to prevent this polio as anyone else, but that is a startling statement and I wondered whether anything other than the actual ability of the companies to produce the vaccine had anything to do with the licensing of any of them.

Mr. PERKINS. I can assure you it did not, sir, and I think the promptness of action by the Surgeon General when it appeared that there might be some defect in certain lots of the Cutter vaccine, and the complete endorsement that the Surgeon General received from the Secretaary in all of his actions pertaining to that, is ample evidence.

Mr. DOLLINGER. Mr. Klein, can you give us the initials of that politician without giving his name?

Mr. HINSHAW. I object to that and I object to the reference as unfounded and rumored.

Mr. DOLLINGER. The papers had it.

Mr. DIES. I want to ask the gentleman if, in his questions, he intends to develop the past record of the Cutter Laboratory?

Mr. KLEIN. I was just coming to that.

Is it a fact, Mr. Secretary, that the Cutter Laboratories at some time in the past had some difficulties with regard to the manufacture of either a vaccine or some pharmaceutical product as the result of which some action was instituted?

Mr. PERKINS. It is my understanding that that is true.

Mr. Larrick of the Food and Drug Administration?

Mr. LARRICK. Yes, 7 years ago we had difficulty with the intravenous solution produced by them.

Mr. KLEIN. Was any action taken by the Government or any governmental agency against the Cutter Laboratories as a result of that?

Mr. LARRICK. The product was removed from the market, Congressman Klein, and a criminal information was filed with the court.

Mr. KLEIN. How long ago was that?

Mr. LARRICK. Seven years ago.

Mr. KLEIN. Was there anything prior to that time that you know of?

Mr. LARRICK. I should say that prior to that time we had, in the enforcement of the Food and Drug Act, a number of instances where products of the laboratory were not in compliance with the law but not in a respect where it would be dangerous to health.

Almost all firms have some trouble in that regard.

Mr. KLEIN. Would you say that anything along the same lines would apply to any of the other five companies that were licensed to manufacture the vaccine?

Mr. LARRICK. Without looking at the record, I would hate to make a categorical statement but almost all of them have had over the years some difficulties. The drug business is like any other business, there are human beings involved but, by and large, this group in my opinion is a group of first-class drug manufacturers.

Mr. KLEIN. Were criminal informations filed against any of the other six?

Mr. LARRICK. Would you give me a chance to check the record?

Mr. KLEIN. Would you submit that for the record?

Mr. LARRICK. Yes.

(The information referred to was later discussed and a summary appears on p. 53.)

Mr. KLEIN. Mr. Secretary, would you think, in view of this prior occurrence, that it was incumbent on the Department or somebody in the Surgeon General's Office to be a little more careful than usual in checking the output for this particular laboratory?

Mr. PERKINS. I am sure that the Surgeon General's Laboratory of Biologics Control knows the full records of these manufacturers, and I will ask him to answer the question or refer to anyone else he wishes.

Dr. SCHEELE. Mr. Klein, our staff who handled the biologics control problems were aware of this other problem.

We first licensed Cutter in 1914, I believe it was. They were the eighth licensee after the passage of the act in 1902. In that time

period up to the present time they have had over 60 different biologic products licensed. Of those, about 18 or 19 are vaccines. They are making a very extensive series of biological products that we are interested in and they are making also a very extensive series of animal biological products including some virus vaccines. They had an excellent record throughout this entire production period.

As far as we are concerned, there was only one instance in which a major question was raised about one of their products and that was one in regard to the material called fibrin foam. This was a material made from blood plasma. It was not known by the men who did the research on this particular product in one of our universities that this particular material could be a carrier of hepatitis virus, even as we did not know in the beginning that human plasma used for treatment of shock would also turn out to be a carrier of hepatitis virus.

As soon as it was discovered, as soon as the scientific fact became apparent, this particular product was not then used. This was a scientific discovery. It was not known before this particular item was developed by one of our major scientists in one of our major universities.

You will recall that even in the period of wartime in Korea we had to use plasma even though we knew there were certain elements of risk. During this period of time we were trying desperately to develop the use of the so-called blood extenders, blood expanders, as substitutes for treatment of shock.

What I am trying to say essentially about the fibrin foam is that this was not related to any accident or controllable situation as far as Cutter Laboratories were concerned. So they did have over the years an excellent record and our staff were in touch with them and did visit their plant from time to time and knew the staff and knew the staff's competence.

Our staff did have confidence in them.

Mr. KLEIN. I do not want my questions, doctor, to indicate a thought in my mind that there is anything wrong with Cutter or anybody else here.

Mr. O'HARA. Will the gentleman yield?

Mr. KLEIN. I will be glad to.

Mr. O'HARA. The fact that a criminal information or indictment was filed, what happened? Were they convicted, found not guilty, or what?

Mr. PERKINS. They pleaded nolo contendere.

Mr. LARRICK. Six hundred dollars fine.

Mr. O'HARA. Nolo contendere?

The CHAIRMAN. Mr. Klein has the floor.

Mr. BEAMER. Will the gentleman yield?

Mr. KLEIN. As I was going to point out, I have a couple of questions passed to me by members of the committee.

Mr. BEAMER. Mr. Chairman, are we going to have more than 1 day on this subject?

The CHAIRMAN. We certainly will have to have more than 1 day on this. The questions being asked are not related to the bill. We will have to put the hearings over to next week.

Mr. BEAMER. That was my point, Mr. Chairman. The questions do not seem to pertain to the bills before us.

The CHAIRMAN. The Chair is aware of that but we realize that this is a committee of which the Members of Congress have asked a great many questions.

Mr. HINSHAW. May I call attention to the fact that the gentleman from New York says he has questions that were passed to him by other members of the committee that he wishes to ask?

Do you not think it is proper that the other members ask the questions in their turn?

The CHAIRMAN. I think it is a practice that if some member hands a note and he thinks it is proper at that point, the chairman has never felt it was proper to intervene on that technical a point.

Mr. Klein, do you have other questions?

Mr. KLEIN. Yes.

The CHAIRMAN. Each member of the committee will be given an opportunity to ask questions, even next week, if necessary.

Mr. KLEIN. Mr. Chairman, I would like to point out to the gentleman from Indiana that I believe this is very pertinent to the purposes of this bill.

We are asked to authorize $28 million to be spent for this program. It seems to me if this money is not going to be used properly, we should indeed go into all phases of the problem very exhaustively.

Mr. BEAMER. Would the gentleman yield?

I was not referring to this discussion. I was referring to the initials and other unfounded rumors that the gentleman from New York apparently was attempting to inject into the hearings.

Mr. KLEIN. If I want to mention the gentleman's name, I will mention it. I am not concerned about initials. I am not going to do it.

The CHAIRMAN. Let us proceed in order. If you have additional questions, Mr. Klein, ask them, please.

Mr. KLEIN. I might say to Dr. Scheele that I have known you a long time, I have known your department and your great work. I am particularly concerned with the questions that we have read in the newspapers about politics entering into this and this helps you as much as it does me if you can clear that thing up in the public's mind.

Were any applications made other than these six for licensing the manufacture of the vaccine?

Dr. SCHEELE. No, sir; there were not.

Mr. KLEIN. If there had, you would have considered them along with the six?

Dr. SCHEELE. We would have based our decision on our knowledge of their ability to carry out the procedure and our estimates of past performance and would have acted probably in the same way.

There are only about 10 firms in the United States that probably have facilities and the staff competent to do this kind of vaccine manufacture. As a matter of fact, I believe the National Foundation did appeal to that entire group of 10 and it was only the 6 who felt that they were in a position to move forward in making the materials.

Mr. KLEIN. There was something in the paper this morning, I believe, about the fact that these reexaminations had been completed. Would you say now that all of the vaccines will be released so that they can be used throughout the country?

Dr. SCHEELE. No, sir; the status is essentially this: We cleared a number of lots of vaccine from five of the manufacturers. The sixth

of the manufacturers has not as yet had any vaccine. Some of these were used.

There were six cases of polio that occurred in children who had Cutter vaccine. We could not tell whether that meant there was something wrong with the Cutter vaccine or whether these were coincidental cases. There is polio in the United States all year and there was in California at the time when these cases were occurring.

So, as rapidly as we could, we directed Cutter to pull all their vaccine off the market. We did not attempt to ascertain which lots were involved at that time. The important thing was to think of safety and to get it all back and to stop vaccination with it and then try to untangle just what the problems were on the vaccine.

Mr. KLEIN. Are you able to do that, Doctor?

Dr. SCHEELE. That is in progress, sir. The tests on tissue culture and on monkeys on the various lots of Cutter vaccine are in progress, not only in our laboratory in Bethesda, but I believe in 14 independent laboratories so far, mostly in universities around the country.

Mr. KLEIN. That is a question of testing. I thought you had requested them to call back all vaccine.

Dr. SCHEELE. The testing is to try to ascertain whether or not there was active virus in the vaccine.

Mr. KLEIN. Have they to date been able to call back all the vaccine which they have sold throughout the country for purposes of vaccine?

Dr. SCHEELE. Yes, sir; we believe that they have.

Mr. KLEIN. Could you now say that there is no reason for any parent throughout the country whose child is in a position to be inoculated to hesitate because of the fear that it might be part of the Cutter vaccine?

Dr. SCHEELE. We cannot guarantee that every last cc. of the vaccine was turned in by an individual physician who may have had it. He may have thrown it into the garbage. It may not have been sent back to the Cutter plant. However, the data on the amounts returned and the data that we have been able to gain on the immunizations given lead us to believe that most of it, if not all of it, has been returned and is off the market.

Also, the notice that this should not be used is out very thoroughly through medical channels and I do not believe any physician in the United States would give it if any were still remaining.

Mr. KLEIN. It is easily identifiable, the name appears on the bottle?

Dr. SCHEELE. Yes, sir; it does.

Mr. KLEIN. One final question.

Would the fact that that vaccine is being recalled materially affect the amount that is presently available for inoculation?

Dr. SCHEELE. Well, at the present time it is not affecting it materially because we have not been releasing additional lots of vaccine pending the outcome of the studies of processing techniques and testing techniques of all the manufacturers.

However, in relation to all the manufacturers, approximately 10 percent of the anticipated output was, or would in the future have been, Cutter material; that varies from month to month in the projections of the various companies for production.

Mr. KLEIN. Thank you.

Mr. WOLVERTON. Mr. Chairman.

The CHAIRMAN. Mr. Wolverton asked a couple of questions which Mr. Perkins desired Dr. Scheele to answer at the time that Dr. Scheele was out of the room.

You may proceed.

Mr. WOLVERTON. The question that I asked of Mr. Perkins, Doctor, related to the investigation that had been made with respect to the Cutter vaccine.

Did your investigation definitely determine that the six cases that have been referred to in California were the result of the use of the Cutter vaccine?

Dr. SCHEELE. No, sir, Mr. Wolverton, at the moment our investigations have not shown unequivocally that there is a relationship between that vaccine, in terms of cause and effect, causing polio. The data that we have at the moment are the epidemiological data, the study of the incidents of paralytic and nonparalytic polio in children vaccinated with Cutter vaccine.

Those data strongly suggest, they represent presumptive evidence, that there was some problem in 2 lots of the Cutter vaccine out of 9 lots which were out and being used. That is, however, not proof. In Idaho and in California, notably southern California, the numbers of cases occurring in children receiving Cutter vaccine were much higher than would have been expected in that same group of children at that season of the year had they not been involved in the procedure of being vaccinated.

In other words, the total incidence was much higher and this gives cause for the epidemiologists to assess this as evidence of cause. Now, it is presumptive; it is not absolute proof of cause. Beyond that, members of our staff have done a very thorough check of the Cutter plant since this incident. They have gone over their methods of processing, they have gone over their plant layout. They have talked to all of their personnel who have been involved in the manufacturing process. They have tried to reassess their abilities and have tried to see whether they could find anything which would show evidences of a slip along the way.

The report on those findings has not as yet been made available to me. Members of our staff in Bethesda are putting together the data from that visit and I do hope to have that in the fairly near future.

The third phase of the study, and this is a very crucial part of the study, is the actual testing of the lots of vaccine which were released and which were used in both tissue culture, which is one of our methods, and one of our most sensitive methods, and in monkeys to see whether in finished lots of vaccine we can identify, or others who are assisting us can identify, quantities of active virus, excessive quantities of live virus. That would then be rather definite evidence that there was some special problem in these particular lots.

These samples are being tested by the 14 laboratories which have offered to cooperate and help us by studying blind samples.

A member of our staff has affixed special labels which are coded. Not only are they testing the material from Cutter, but they are testing other materials without knowing which is which. Then they will match the key and we will have knowledge as to whether or not active viruses have been found in these Cutter materials; that will take some time because these tests take quite some time to complete.

Mr. WOLVERTON. Did your investigation show how many children had been injected with this Cutter vaccine?

Dr. SCHEELE. Yes, sir, Mr. Wolverton, we have fairly good data on the numbers of vaccinations. It may take me a moment to find that in my notes here.

Dr. Sebrell, do you have that at the tip of your tongue here by any chance?

Dr. SEBRELL. Around 400,000, I think.

Dr. SCHEELE. Roughly, 400,000 children were vaccinated. The numbers of children who have developed polio in paralytic form are 56. In non-paralytic form there are fewer, and these are sometimes open to question as to whether or not they are polio.

Nonparalytic poliomyelitis is a diagnosis based on the fact that the child had a runny nose, had a headache, may have had diarrhea. Usually they do a spinal puncture to see if it might be polio.

This is a presumptive test and if the cell count is up, they say it's polio but it does not prove it.

So we have here as of noon on the 24th, 56 children who have developed polio in this group. Only some of these children had some material from two of these lots. Some of these cases if we assume that the two lots had active virus or were in some way contaminated, and we are not in a position to say they were, may have caused polio. We can also assume that other lots were all right and that some of these were coincidental cases that would have happened anyway.

What I am saying is that 56 would not be the total that would have been caused by vaccine.

Mr. WOLVERTON. Is that a usual circumstance resulting from the use of vaccine such as we have here where 400,000 children had it and yet you had found that there were only apparently few cases, 56 in number, that developed?

Does that happen with respect to other types of vaccine?

Dr. SCHEELE. Yes, sir; it has happened.

As one looks back at history, there were rather serious problems that arose in smallpox vaccination with many deaths.

The introduction of yellow fever vaccine found many unsolved problems and many, many deaths. I do not know how many there might have been.

Mr. WOLVERTON. How would you account for the fact then that it happened in these few cases with the Cutter vaccine and not with that which was manufactured by any of the other laboratories?

Dr. SCHEELE. That is one of the mysteries or problems that we are trying to unravel at the moment. We are trying to identify what might have beeen done differently by Cutter than was done by others.

Mr. WOLVERTON. When they make up a batch of this vaccine how many does that usually take care of, how many children?

Dr. SCHEELE. The amount that any given laboratory produces as a lot, as a batch, varies.

Dr. Sebrell, can you tell us what the range in lot size is?

Dr. SEBRELL. The lot sizes vary among the six manufactures very widely, according to the kind of equipment they have. Some are large and some are small plants. They vary from around 40 liters to 400 liters.

Dr. SCHEELE. A liter is a little more than a quart, it is 1,000 cubic centimeters.

Mr. WOLVERTON. What I am trying to find out is how many children other than these 6 could possibly have been vaccinated with material manufactured in the same batch that was used for these 6.

Dr. SCHEELE. Do you have the Cutter?

Dr. SEBRELL. I think perhaps I can answer Mr. Wolverton's question.

There were eight lots of Cutter vaccine that were utilized in the inoculations of the four-hundred-thousand-odd children. These have been analyzed according to what happened in each of the eight batches. In 4 of the 8 batches there were no cases of poliomyelitis.

Among the other four batches occurred the sixty-odd cases to which Dr. Scheele has referred. These are concentrated very largely in two batches. These two batches are further broken down.

The large batch that is prepared, as it is filled into the vials, becomes what they call filling lots. They do not fill lots all the same day and they fill vials of varying sizes. Therefore, a manufacturing lot winds up on the market as four or more filling lots. This gives you, if you can distinguish between the filling lots, you help distinguish between, if an accident occurred in the plant, whether it occurred as the vials were filled or whether it occurred in the manufacturing process.

Most of these cases are concentrated in two filling lots. However, this does not prove the point at all.

I think I should clarify the situation here that this does not prove that the whole thing is involved in an accident in the Cutter plant.

There are other factors to be considered here very seriously and we are in the middle of the investigation and it cannot be answered completely at this time.

Mr. WOLVERTON. Well, the difficulty that I have in getting an understanding of this arises from the fact that I do not seem to be able to learn how many children were injected with the same vaccine that produced these unfortunate results in six of them.

I assume from what you say that if there were 8 batches and there were 400,000 children on whom this vaccine was used, that would make about 50,000 for a batch.

Now, you referred to two batches that were under suspicion. If that is true, they would take care of 100,000 children, and yet there are 56 that show up.

How could it be possible that you could use that amount that would take care of 100,000, if it were all used, and only 56 of them would show up? What would be the basis that it would have this effect on some and not on all?

Mr. SCHEELE. Mr. Wolverton, it could be several things. It could be the fact that there were only a few vials that contained the virus and those were vials that were used on those particular children.

Another possibility is the fact that the amount of virus may have been very small but it may be that those particular children had lower natural immunity levels than other children and therefore could not sustain that particular dose level.

In other words, what I am saying is that it is possible that the other children had some antibodies and the very tiny level of virus that was there was neutralized immediately and it meant nothing to

them. But those few who developed paralytic polio did not have enough antibodies and therefore could not neutralize them.

Now, this is all theory; there is no proof of this.

Mr. WOLVERTON. Were you able in your investigation to get any of the identical product?

Dr. SCHEELE. Yes, sir, because a considerable amount of the identical product in the two lots that appear to be related to the groups of children who had a higher incidence than one would have expected naturally was not used. Our stop order on the 27th of April kept rather substantial amounts of those same lots from being used.

Mr. WOLVERTON. Was it the same physician who had injected the vaccine that caused the unfortunate results in these six cases or was it a different physician?

Dr. SCHEELE. No, sir; these were widely scattered cases.

The first one that came to our attention was in Chicago. It was the only case in Chicago.

The other cases were scattered in California. There was 1 in Napa Valley, there was 1 in Ventura, there were 2 in San Diego and there was 1 more possibly in Berkeley or some other point.

Mr. WOLVERTON. Were you able to ascertain whether the physician who inoculated the Chicago child or the San Diego or any others had also used the same material on other children?

Dr. SCHEELE. I am sorry to say that I do not have full information on that but some of these children, in San Diego for example, they were children in the first and second grade program that was being conducted in the public schools, so substantial numbers of other children did receive vaccinations by the same physicians from the same lots in that area.

Mr. WOLVERTON. And yet, in their case, it did not develop?

Dr. SCHEELE. That is correct, sir; yes, sir.

Mr. WOLVERTON. That leads me to ask whether there was a deficiency in the formula.

I will put it first this other way. In these 2 batches, so to speak, that you examined, as compared to the other 6 that were put out by the Cutter people, did you find that there was any difference in their makeup or manufacture?

Dr. SCHEELE. I would have to pass that question to Dr. Sebrell.

Dr. SEBRELL. As I indicated, Mr. Wolverton, the investigation is still going on and it is difficult for me to speak positively because the results are still coming in every day.

Mr. WOLVERTON. Pardon me, I am not a chemist, I am not qualified to speak and maybe for that reason you will think my question is foolish.

Dr. SEBRELL. Not at all.

Mr. WOLVERTON. What I am trying to find out is this: If this vaccine that was used on these 6 children produced the unfortunate result that it did, was it because of the way it had been manufactured, was it because of the Salk formula? Just where was it?

Now, if you compare those 2 that you refer to as having been the ones that were used as against the 6, is it not possible to tell immediately? Does it require an investigation for a long time such as this to determine whether they were both alike or not?

Dr. SEBRELL. I am afraid it does. Perhaps our problem is more complex than has been indicated here. Many of the vials contained 9 doses, the vials provided with the vaccine. That means that out of every single vial, there were 9 children inoculated with the same material.

So far as I know, there have been no two cases that occurred from the same vial of material.

Nine children were inoculated; 1 child developed polio, and why did not the other 8? This is a question to which I have no answer at the moment.

Mr. WOLVERTON. That does not quite go to the question that I put. That is a very important observation that you are making, which to me would seem to indicate that there was something maybe in the child himself or herself that resulted in this unfortunate circumstance.

For instance, how many injections do you give to a child?

Dr. SEBRELL. They are getting one injection at the present time. They will get three eventually.

Mr. WOLVERTON. I thought they were to have 2 and in some instances I read of 3.

Dr. SEBRELL. The whole series calls for three injections at varying intervals.

Mr. WOLVERTON. Do you give the three because the first is not necessarily effective?

Dr. SEBRELL. No, the immunity builds up rather slowly. You get some immunity from the first dose, added immunity from the second dose, and then it requires the third dose to give you full immunity.

Mr. WOLVERTON. If these 6 children, which we will use as an illustration, developed a paralytic form after having had 1 injection. I assume, could it be that they might have had that condition arise if they had not taken the vaccine?

Dr. SEBRELL. That is possible. There are many possibilities.

Mr. WOLVERTON. In other words, I am trying to find out whether there is any deficiency in the formula of Dr. Salk.

Has there been any change of opinion in that respect as to the efficiency of it or is it a matter of manufacture, and if it is a matter of manufacture, how do you test each batch?

Now, I will tell you why I have the thought that I have in this. Some many years ago when I was more active in the practice of law than I am now, it fell to my lot to defend a man who at that time was president of the pharmaceutical association, a national association, one of the outstanding chemists, and he operated a manufacturing establishment. On some of the pills that he put out, and I do not know what it was for because it has passed out of my mind, some of them were not up to par. Some of them were and some were not.

Is it possible that in making up the batch that some could be all right and some would not be all right of the same batch?

In that case there was nothing to be said against the honor, integrity, or ability of the man. It was entirely a matter of manufacture that in getting those pills in shape they did not, evidently, get the full formula into the pill.

Can that sort of thing happen?

Dr. SEBRELL. Let me say that according to everything I know, I think the Salk vaccine is a good vaccine. There is nothing the matter with the Salk formula, according to every bit of information I have.

Whenever you move from a laboratory process to a large industrial process, you inevitably introduce complications. This process moved very rapidly from a laboratory process into a commercial process. Every safety device that could be devised was put on that product. Nevertheless, when you introduce changes of this kind, you use varying volumes, varying temperatures, varying concentrations, you introduce new problems, and the whole process has to be thoroughly studied and is being thoroughly studied and reexamined to determine how we can make it as safe as it is possible to make it.

Now, all biological products have some danger to them, as Dr. Scheele indicated. You can never say anything is perfectly safe but you put every safety device around it that you can and determine what the risks are.

Mr. WOLVERTON. What tests are made in the plant itself, if any, to determine whether the manufactured product is identical with and the same as the Salk formula calls for?

Dr. SEBRELL. It is made according to strict requirements that are issued under the Biologics Act. The plant processes are carefully inspected. The tests are made along the line of production, tissue culture tests, and monkey tests.

Mr. WOLVERTON. Who makes those tests?

Dr. SEBRELL. They are made by the manufacturer.

Mr. WOLVERTON. Does the Government itself have any individual present to supervise or to examine those tests?

Dr. SEBRELL. The protocols of those tests are sent to us for examination.

Mr. HALE. What is sent to you?

Dr. SEBRELL. The protocol, which is the details of all the tests that are done in the plant. This is a bulky document that includes complete detail of all the tests. That is sent to the laboratory for biological approval before the lot is released. That is done on every lot manufactured.

Mr. WOLVERTON. I will not pursue the question any further, I will merely make this slight observation. I agree with what Mr. Klein has said about this being such a wonderful discovery in this century.

It is certainly unfortunate that after the great promise that was made with respect to Dr. Salk's formula that this situation should have developed that creates, as he has said, a feeling on the part of 30 percent of the people in New York that it might not be wise for their children to get vaccinated.

I think what we have to do, instead of complaining, even though we regret what has taken place—I think we have to build up confidence in people.

Just what the way is to do that, I do not know. If the scientists are all satisfied that the Salk vaccine is a remedy, which they evidently are as a result of field tests, then let us get to it to establish that in the minds of the people in a way that they will not be so upset.

All that has been going on, talking by this one and that one and the other one, is creating doubts in the minds of the people and what I would like to see is something very, very definite done that will establish confidence. If it is true that no vaccine will be 100 percent

perfect with every individual and that there can be some skips, so to speak, as has been referred to in smallpox and yellow fever, and these other things, maybe we had better know how slight that possibility is, so that we will know that, in the overall picture, here is something that can be highly beneficial.

I am just trying to find out whether there is a deficiency in the formula of Dr. Salk or whether it is in the manufacture of this formula.

Dr. SEBRELL. So far as I can tell, Mr. Wolverton, it is not in the formula, it is the difficulties of manufacture, a very difficult thing to manufacture even under the best of circumstances.

Mr. HARRIS (presiding). Mr. Carlyle?

Mr. CARLYLE. No questions.

Mr. HARRIS. Mr. Hinshaw?

Mr. HINSHAW. Mr. Chairman, I would like to inquire again as to those figures which were published as to the probability of immunity of those who would take a complete course of vaccine.

Dr. SCHEELE. We would have to get that for you.

Mr. HINSHAW. I believe, if memory serves me correctly, it was from 60 to 90 percent.

Dr. SCHEELE. I was thinking of giving you something a little more scientific than this gross estimate of end result.

There are three types of poliomyelitis viruses called types 1, 2 and 3. The vaccine is made up by the use of those three viruses killed with formalin and preserved in certain other ways.

Type 1 virus infection is our commonest form of polio infection. In the case of the field trial tests, it appeared that the vaccine being used at that time was approximately, so far as one could build a round number on it, 60 percent effective.

For types 2 and 3, it was 80 to 90 percent effective.

This means in effect, then, if in any community where there was type 1 virus at a given moment, more children who had been vaccinated came down with natural polio than would have, let us say, if it had been type 2 or type 3.

Mr. HINSHAW. When you speak of type 1, type 2, and type 3, are you referring to paralytic or bulbar polio?

Dr. SCHEELE. No, sir; I am speaking now about identifiable types of viruses. Bulbar refers to the effect of the virus on the human body. We may have polio virus in our bodies with no signs or symptoms. The child or adult may go on without any problem. In fact, every one of us, certainly every one of us in the cities, is exposed to and takes in within our own bodies a lot of polio virus every year. This is why we develop natural immunity.

This is why, as years pass, we get older and get to the point of age 40 or 45 or so no more polio occurs because we have antibodies and we have lost susceptibility.

Another form of polio may be this sort of minimal thing which I mentioned, no muscle weakness, no difficult breathing, but only some superficial things like a runny nose, diarrhea, headache, and increased spinal fluid cell count. This is called nonparalytic polio.

Then there is polio which attacks the nervous system and therefore, causes weakness in certain muscles. It may be limited to an arm or 1 or 2 muscles in the leg or back or some portion of the body.

Then there is the most serious form in which there is involvement of the brain, often affecting the breathing center. This is called bulbar polio because of the portion of the brain it attacks. Frequently there is necessity for placing such a person in a respirator to help him breathe artificially and the possibility, in some of those cases, of death.

Mr. HINSHAW. Is it possible for a single type, such as type 1, to cause all of those forms of polio?

Dr. SCHEELE. Yes, sir.

Mr. HINSHAW. And type 2 may cause them and type 3 in turn may cause them?

Dr. SCHEELE. Yes, sir, although there are in the types 1, some of the type 1's are somewhat more virulent. They may cause a bit more paralytic and bulbar than type 3.

We do not know what the ratios are. We cannot say that 90 percent of the bulbars and 90 percent of the paralytics are in type 1 compared with types 2 and 3, but there is usually more virulence in the type 1 and they will turn up more often in the typings done on cases which are going in any particular epidemic.

Mr. HINSHAW. Now, you say that even after inoculation it can be expected that 40 percent of those inoculated may suffer some form of polio or another from type 1 virus?

Dr. SCHEELE. Yes, sir. This would be the case if the vaccine in use today provided exactly the same amount of protection that the vaccines used during the field trial did.

Now, there are some scientific facts here which have a bearing on this. There is a possibility that the vaccine being used today is somewhat more effective against type 1. It is likely it is more effective against type 1 than was the field trial material.

During the field trials, it was thought that the use of merthiolate as a preservative in the finished lots of vaccine to hold down the growth of molds or bacteria that might be there, as an antiseptic, as it were, was a procedure that was important to follow. All of the field trial vaccines contained this material.

It was found, however, early last winter, and there was some suggestion of this even in the late field trial period, that the merthiolate seemed in some way to be affecting the part of the vaccine called antigen. This is the material which when injected into the body causes it to develop antibodies. It somehow made it less able to work.

Mr. HINSHAW. Yes, but the thing I am trying to develop, Doctor, is that even after the full course of immunization shots, it is to be expected that a certain number of those who have received the full course will suffer this polio?

Dr. SCHEELE. Yes, sir; that is correct.

Mr. HINSHAW. In one form or another?

Dr. SCHEELE. Yes, sir; that is correct.

Mr. HINSHAW. And that it is not a complete immunization for all children who receive it?

Dr. SCHEELE. That is correct and it will vary from child to child. Some will respond better than others with exactly the same vaccine.

Mr. HINSHAW. I think the public ought to understand that fact, that it is not perfect, not 100 percent, and has never been so advertised.

Dr. SCHEELE. That is true.

Mr. HINSHAW. Now, you say in California there were some 400,000 doses?

Dr. SCHEELE. They were not all given in California.

Mr. HINSHAW. Well, from the so-called Cutter Laboratory?

Dr. SCHEELE. Yes, sir.

Mr. HINSHAW. There were 400,000?

Dr. SCHEELE. Cc.'s, cubic centimeters. Each cubic centimeter represents one dose.

Mr. HINSHAW. And some 56 children have suffered some form of polio since that shot?

Dr. SCHEELE. Yes, sir.

Mr. HINSHAW. Can you say what degree of immunization should be brought on by a single first shot of vaccine?

Dr. SCHEELE. No, sir; I cannot tell you what level it would be in relation to the three in terms of proportion but I can say this very positively, and I have talked to Dr. Salk about this within the last few days as a result of an inquiry by your chairman.

Dr. Salk informs me that in most children, the first injection gives a rather substantial degree of immunity and a rather lasting degree of immunity that will last for several months.

It is preferable to have the second dose because the second one has an enhancing effect on the immunity level and then finally, after 7 or 8 months, the third one, which is called the booster dose, which gives an additional level of antibody level and undoubtedly will increase the actual time that it will last.

Mr. HINSHAW. How long does it take for that level to build up from the antigens or antibodies that are created in the system?

Dr. SCHEELE. Normally, it would take, well, it is an increasing thing with the passage of time. It would attain its maximum or nearly its maximum elevation probably in about 4 weeks after the first injection.

Mr. HINSHAW. In about 4 weeks?

Dr. SCHEELE. Yes, sir.

Mr. HALE. Four weeks from the first dose?

Dr. SCHEELE. Approximately; yes, sir.

Mr. HINSHAW. The maximum immunization from that shot would b e obtained in about 4 weeks?

Dr. SCHEELE. Yes, sir.

Mr. HINSHAW. When did these cases show up, in how many days or weeks?

Dr. SCHEELE. Most of them showed up, had some first little sympton, in 7 or 8 days, and those that developed paralysis developed it 2 or 3 days later.

In other words, a spread of about, well, if we count the time that they had for first elevation of temperature, first fever, 7 or 8 days on the average. But there has been some spread of 8 or 9 or 10 days.

Mr. HINSHAW. Then they could not have achieved much immunization by the time that polio showed up?

Dr. SCHEELE. That is correct.

Mr. HINSHAW. How long after the injection of live polio virus into, for example, a rhesus monkey is the polio able to be recognized? I mean in the same way we recognize it in children.

Dr. SCHEELE. I cannot cite the experiments that have been done in monkeys but generally speaking it is held that the incubation period

of polio runs from about 3 to 31 days, with the majority of the infection showing in the period about 7 to 10 days so that the 3-day occurrence, 3 days after challenge or 31 days after challenge is a rare situation.

Mr. HINSHAW. By that time there has been very little buildup of immunity in these children?

Dr. SCHEELE. Generally speaking, that would be correct, but it will vary from child to child.

Mr. HINSHAW. Therefore, unless they receive live virus in the vaccine, which I suppose is remotely possible, or receive the infection from some other sources, it is very difficult to tell, is it not?

Dr. SCHEELE. Yes, sir; it would be very difficult to tell.

Mr. HINSHAW. Would you be able to give me the statistics to say what proportion of children in my home State of California between the ages that the children were who received this vaccine would normally be expected to have polio at that time of the year?

Dr. SCHEELE. I do not have those data but we can have that developed and submit it to you.

Mr. HINSHAW. It is a significant number, is it not, because in California summer comes a lot sooner than most of the United States?

Dr. SCHEELE. Yes, sir; that is true.

I can give you this report which is for the week ending May 14.

California, since January of 1955, had a total of 45 cases reported, of which 25 were paralytic. By the end of May 14, California had 45 cases, roughly half of which, 25, were paralytic.

Mr. HINSHAW. That is total cases?

Dr. SCHEELE. That is total cases, reported cases.

Mr. HINSHAW. How many of them received the Salk vaccine?

Dr. SCHEELE. I have misplaced my sheet of paper on which I had those data.

Mr. HINSHAW. I think it is very important to know because, to my knowledge, there is polio in California at this time of year, in April and May, as well as in the summertime.

Dr. SCHEELE. Yes, sir.

Mr. HINSHAW. And it is elsewhere in the United States and normally, without any vaccine, there would be some number of cases. I do not know what it would be but some number would be expected.

If the climatic conditions were unusual, there might be more or there might be less?

Dr. SCHEELE. That is correct. This situation varies from year to year for the country as a whole and it varies almost more from year to year for localities. There is no predictability pattern.

Mr. HINSHAW. I think that it should be shown, a maximum and minimum expectancy, without vaccine.

Dr. SCHEELE. I can answer your earlier question, I have found my paper.

There were 25 Cutter-vaccinated children in California who developed polio.

Mr. HINSHAW. Mr. Chairman, may I carry on at the next meeting?

The CHAIRMAN. Very well.

Before we adjourn, the Chair understands that there is an extremely important departmental conference this afternoon, and it will be neces-

sary for members of the Department and the technical staff to be present for that conference.

If it is possible for the Department to appear Friday morning, we should like to continue this particular part of the hearings on Friday morning at 10 o'clock.

Is that all right?

Mr. PERKINS. I certainly can and Dr. Scheele will certainly try to, depending on whether or not there are any further meetings growing out of the meetings of yesterday and today.

Dr. SCHEELE. Yes.

The CHAIRMAN. Will you be in a position, Mr. Perkins, to say whether or not Mrs. Hobby might be present at that time?

Mr. PERKINS. She might be. It would depend on the status of her husband's health.

The CHAIRMAN. Very well; the committee will meet again at 10 o'clock Friday.

Dr. SCHEELE. Mr. Chairman, may I say one additional thing for the record, an extension of the comments on the protective value of the vaccine and the protective value of the first injection?

There has been some misunderstanding on the part of some parents who somehow or other have gained the impression that if their child has received only one injection, he may have a greater susceptibility to polio than if he had had none.

In other words, the fact of inability to go on for the moment with the second dose and later with the third dose may have increased his jeopardy to polio. We can say very positively that the children who have had their first injection will develop immunity in most cases which will give them an advantage. In other words, there is no increased hazard by virtue of having had that first injection.

The CHAIRMAN. I am very glad you made that statement, Dr. Scheele, because a great many questions have been asked as to whether one shot only was dangerous if the children did not get the others.

Dr. SCHEELE. Yes, sir.

The CHAIRMAN. I think that should be quite reassuring to a great many people.

Mr. HINSHAW. I would like to say before we close this meeting that I have regretted exceedingly that any politics have been brought into this hearing and I am sure that is the sentiment of the great majority of the committee.

Mr. WILLIAMS. May I ask one question, and this is in line with what Dr. Scheele has just told the committee.

The CHAIRMAN. Yes.

Mr. WILLIAMS. Has it been determined as to the duration of time for which this will immunize a child if he is given the correct number of injections? Is it a lifetime immunization or is it for a period of years?

Dr. SCHEELE. There is no way, really, to determine that except to have that lifetime pass. Dr. Salk has given material to some children as long as 2 or 3 years ago and they are still maintaining a very high antibody level. No one can predict whether that is going to last for 10 years, that high level, or 20 years or 30 years. Time alone can answer this question.

We hope, of course, that it will last and if it is not lasting, it is a simple enough matter to have a booster. This is the case of what we do in immunization against typhus and typhoid fever.

Mr. WILLIAMS. That has not been determined?

Dr. SCHEELE. That has not been determined.

The CHAIRMAN. The committee stands adjourned.

(Whereupon, at 12:25 p. m., the committee recessed, to reconvene at 10 a. m., Friday, May 27, 1955.)

POLIOMYELITIS VACCINE

FRIDAY, MAY 27, 1955

HOUSE OF REPRESENTATIVES,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D. C.

The committee met, pursuant to recess, at 10 a. m., in the committee room, New House Office Building, Hon. J. Percy Priest, chairman, presiding.

The CHAIRMAN. The committee will come to order.

We are continuing hearings this morning on the bill H. R. 6286, the "Poliomyelitis Immunization Assistance Act of 1955" and also the bill H. R. 6207 to amend the Public Health Service Act to strengthen the controls over biological products.

When this committee adjourned on Wednesday, Mr. Hinshaw was asking some questions that were of vital interest to him and to the committee. It is the understanding of the Chair that Dr. Scheele has a brief statement, more or less bringing us up to date, and perhaps Dr. Sebrell will supplement that statement as far as the National Institutes of Health are concerned. I think it would be better if we were brought up to date, first. We are aware from reading the newspapers that a committee of scientists has been appointed, and that the members of the committee have accepted responsibility to work out problems relating to the purity and safety of the Salk vaccine. Other developments have taken place also.

Before we resume the questioning, I should like to ask, Dr. Scheele, if you prefer to make a statement at this time.

Dr. SCHEELE. Mr. Chairman, and members of the committee, we would like to make a statement to try to put some of the events on vaccine in the proper perspective. However, we know that members of the committee have questions to ask and we do not want to interfere with those questions by taking unnecessary time.

Mr. DIES. I think, Mr. Chairman, he ought to bring this up to date.

The CHAIRMAN. I am sure Mr. Hinshaw will relinquish his questioning time temporarily so that we may be brought up to date. It may be that the information you have there answers some questions that might come later. So you may proceed to do so at this time.

STATEMENT OF DR. LEONARD A. SCHEELE, SURGEON GENERAL

Dr. SCHEELE. The nature of the questions that were posed in the hearing the other day led us to feel that if we could establish some of the sequence of events on the vaccine, it might establish in advance some of the answers to the questions that the committee may have. I would like to make a brief summarizing statement about events of the last day or so.

As you may know, all six manufacturers have accepted the revised Public Health Service standards for making poliomyelitis vaccine. This is good news, but I must emphasize that the program will go ahead only as fast as safety permits. The rate of injections will not be as high as we had all originally hoped. Regrettable as any delay in the program may be, we must all bear in mind the vital importance of making sure that this protection is given to our children under standards as safe as science can make them.

The recent occurrence of paralytic poliomyelitis among some children who received the vaccine underscores the need for such precautions. As soon as we learned of this outbreak, we took immediate steps, as the committee knows, to recall the product of that one manufacturer. Then, cooperating closely with the Nation's leading scientists, we launched an exhaustive study of the many possible explanations for the occasional instances where the vaccine may have transmitted polio. This unexpected occurrence led to scientific discussions at which several problems arising in the manufacturing process were reviewed. This led to a series of careful plant inspections, the results of which in turn caused a holdup in approval of additional vaccine pending details of the final study of the data collected in the plants. The Public Health Service and its consulting scientists have now completed the study of the vaccine and testing methods used by the manufacturers. Our findings are the basis for the revised standards which we are confident will give increased assurance of the vaccine's safety. These standards are now in effect. Vaccine will be released for the program as fast as it is found to meet the revised criteria.

It is unlikely that our original expectations for mass vaccinations this summer will be fulfilled.

The CHAIRMAN. Will you talk just a little louder, Doctor?

Dr. SCHEELE. Yes. But I am sure that every parent will understand and appreciate the necessity for making it as certain as humanly possible that all polio vaccine is as safe as medical science and modern industry can make it.

The Salk vaccine is a good vaccine. It is as safe as science today can make it. It was proved 60 to 90 percent effective in the field trials last year. No vaccine is 100 percent effective. No vaccine will prevent all cases of polio, just as no vaccine can prevent all cases of smallpox, whooping cough or diphtheria. These facts should be clearly understood. But they should not obscure this basic finding of scientists working in the field.

The child who is innoculated with this vaccine runs a far smaller risk of contracting paralytic polio than a child not vaccinated. Based on last year's field trials, the risk of developing paralytic polio in children 5 to 10 was calculated to be 1 in 6,000 among those vaccinated and 1 in 1,700 among those not vaccinated. In other words, the risk has been less than one-third as great after vaccination.

Even though there has been this delay to assure greater safety, we have made very rapid progress in the vaccination program. Manufacture of this vaccine is difficult and intricate. This process has been rapidly broadened from the limited work of the laboratory or pilot plant to the scale needed to vaccinate millions of children.

In order to assist us in studying the lots of vaccine being submitted by manufacturers for release, we have appointed a panel. The chairman of this panel is Dr. James Shannon, Associate Director of the National Institutes of Health, with the membership consisting of Dr. Jonas Salk of the University of Pittsburgh; Dr. Thomas Francis, Jr., University of Michigan; Dr. David Bodian, Johns Hopkins; Dr. Richard Shope, Rockefeller Institute for Medical Research; Dr. Joseph Smadel, Walter Reed Medical Center; and Dr. William Workman, Chief of the National Institutes of Health's Laboratory Biologics Control, who is secretary. This panel met throughout the day yesterday and last night. They discussed standards further. They met with representatives of each of the manufacturers, with management, with production and scientific staff, and at approximately 2 o'clock this morning, or 2:30 this morning, arrived at full agreement with the manufacturers on the handling, the manufacture, and the testing of vaccine in the future.

We feel that this is a wonderful step forward. We have never had a finer working relationship with any group of people than we have had with the manufacturers themselves, all of them, in their cooperation with us. That is the picture of the last 48 hours.

I would like to ask Dr. Sebrell, now, to describe some of the events leading up to that.

The CHAIRMAN. Before Dr. Sebrell begins, I want to state this for the record: I appreciate, and I believe everybody knowing the circumstances appreciates, the fact that the Public Health Service and the Department have not been willing to sacrifice safety for speed in carrying on this program of inoculation. I think personally that the appointment of this committee, with the agreement of all of the manufacturers to conform to the new and more rigid standards of safety, is a real achievement. I think that the public should appreciate the fact that that has been done, and that safety will not be sacrificed for any other purpose.

I commend you, Dr. Scheele, and others who have pursued that policy. I believe it is one that the public generally will appreciate.

Regardless of all of the developments in this program since it was first announced, regardless of confusion that has existed in many minds, I think everybody can appreciate the fact that you have set rigid standards, that you are enforcing those standards, and that the manufacturers have agreed to accept those standards requiring more rigid testing methods.

I wanted to say that for the record, because I believe it is work well done. I am aware that most of you gentlemen before the committee this morning were up until 4 o'clock this morning, and you did not have very much sleep last night in hammering out that program. I express this commedation because I think it is well deserved.

Doctor, I would like to follow immediately with a statement from Dr. Sebrell. Mr. Bennett, of Michigan, has to leave here at 10:30, and he had 2 or 3 questions he wanted to direct to Mr. Perkins in connection with the bill that is before us. If you could withhold until Mr. Bennett asks those questions, Doctor, to give him an opportunity to obtain his transportation, either a train or plane, I shall deeply appreciate it.

Mr. Bennett, will you ask your questions now?

Mr. BENNETT. Thank you, Mr. Chairman. I want to join with you in commending Dr. Scheele for the outstanding work that he has been doing to solve this very perplexing problem of safety in the use of this vaccine. I think we can all agree that safety is the prime factor, and no one, regardless of their deep desire to get the children inoculated wants to sacrifice safety for speed.

I think you should be commended, Doctor, for the spendid efforts you have put forth, together with the medical profession, the experts who have been working with you in tihs field. I think most people in the country who are aware of your efforts feel deeply grateful.

I want to ask Mr. Perkins a question or two about the bill.

After the question of the safety of the vaccine has been resolved, and we decide to go ahead with the program of vaccinating the children of this country, the question in my mind is what is the best manner in which to proceed. You presented a bill here that—and I have not had an opportunity to study it too carefully—on the surface seems to be a rather complex and involved method of meeting what seems to me to be the kind of a problem that we ought to meet by a more direct approach.

My first question is this: Do you not think it would be better to have the Federal Government take control of this program, not only as to the allocations of the vaccine, but in the manner of providing rules and regulations as to the priority of its use, and providing all of the funds that are necessary to carry that out?

My reason for suggesting that is this: This is not a program of socialized medicine. It is not a program that is of special concern to any locality or any State. It is a problem of great national concern. To meet it, why would it not be better to have a program of complete Federal control, of complete Federal financing of this program, until every child from birth through high school age has been inoculated?

Mr. PERKINS. Well, it certainly is essential that there be control. It is simply a question of how we go about achieving that control and orderly flow of the vaccine. The program which I outlined to the committee on Wednesday, we think, establishes a voluntary control pattern for the distribution of the vaccine, with the Federal Government assuming responsibility for making an allocation, a fair allocation, of the vaccine to each State on the basis of its child population within all age groups. That plan does call for what you say is necessary, and which we agree is vitally necessary, an establishment of uniform priorities.

From that point on, we believe that as under the program being operated today by the National Foundation for Infantile Paralysis, it is essential that the State health officers be the key officer within the State, or some other designee of the governor. In other words, we do not think a Federal structure inside the State can work.

So, under any program, we think it is an essential element that it focus upon the State health officer as the keyman within the State.

Mr. BENNETT. Why do you say that?

Mr. PERKINS. Because they are the ones that have the experience with respect to the operation of public health programs within their own States. We think it would be foolhardy and would slow the program down tremendously to try and substitute Federal officials within the States for the State officials.

Mr. BENNETT. I do not mean to substitute Federal officials for State officials. What I mean is that the Federal Government, the United States Department of Health, shall lay down the rules and regulations and determine who is going to handle it and how it is going to be handled, so that you would have complete uniformity in the 48 States. It may be some State departments of health are not set up to handle a program of this kind. In those instances, it seems to me that the medical profession, the medical societies, could be brought together by your Department and handle it according to the standards you lay down. But we have a program here of a matching formula basis, similar to that being used in grants for the study of arthritis, heart disease, and all those other things. Those are all long-range programs.

Here you have a job to be done that you want to have completed as soon as you can, and when you are through with it, it is completed. There is nothing to continue on about. It is a 1 or 2 shot operation. I just cannot see the necessity for passing legislation with complicated formulas, whereby the Federal Government will divide up so much money with various States on a percentage basis and let them go ahead and carry out the program in accordance with their particular laws and regulations. That, it seems to me, is not the way to handle this kind of a program.

Mr. PERKINS. We think we have to divide the problem into two parts, the problem of having orderly flow of distribution, and the problem of paying for the vaccine. What I have indicated is that in our opinion the program proposed in the report to the President does present a pattern of orderly distribution of the vaccine. As for the question of paying for it, there are, of course, an infinite variety of alternatives. The Federal Government could, conceivably, do nothing in the way of assisting in paying for the cost of the vaccine. On the other hand, as you are suggesting, it could conceivably, for some period of time, pay for all of the cost of the vaccine. There a problem would arise, of course, as to the point of cutoff. That is, would you complete the whole 1 to 19 group, or would you continue on as each new group of children is born?

But in any event, the alternative selected under the bill before the committee is that the Federal Government will pay to the States a sufficient amount which would enable the States to assure that no child would be denied vaccination by reason of the cost. Although the legislation may appear complicated, it is actually very simple in terms of what it does. It divides up this $28 million among the States on the basis of their child population and the per capita income, and the States are thereby put in a position, in spite of the fact that their legislatures have gone home, to pay for the cost of vaccine for those who might otherwise not be able to pay.

Mr. BENNETT. I do not see why you bother about how much a State should pay, or how much they might be able to pay, or whether to base it on the per capita income of the State. Here you have a problem of getting every child inoculated with this vaccine. You cannot do it by handing it out to the medical profession promiscuously without some control. It seems to me the control ought to be uniform. While we are spending our time here trying to work out what I think is a complicated matching fund formula, you are going to waste a considerable amount of time, it seems to me, after you have once gotten

ready to go ahead with the entire program. I think you could well give consideration to suggesting some alternative proposal, where the Federal Government would control this program, and where it would finance it, and where, in cooperation with State agencies and medical societies, the thing would be carried through. That, it seems to me, is the proper approach.

That is all, Mr. Chairman.

The CHAIRMAN. Very well, Mr. Bennett. Thank you, sir.

Now Dr. Sebrell has a statement supplementary to the statement made by Dr. Scheele. After that, Mr. Hinshaw will be recognized to continue his questions.

Dr. Sebrell, you may proceed with whatever statement you have to make at this point.

Dr. SEBRELL. Thank you, Mr. Chairman.

STATEMENT OF DR. W. H. SEBRELL, JR., DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Dr. SEBRELL. Mr. Chairman, and members of the committee, it is a real pleasure to appear before you here this morning to tell you the highlights of this story of the development of the Salk poliomyelitis vaccine, because it is, I think, a very thrilling story. I will be as brief as I can, to save your time, and touch only on the important highlights. It is a thrilling story because it represents great progress in medical research, and it is also a great American story, because it represents a close cooperative and continued effort between a scientist on the one hand, a brilliant scientist, in a place where he can have free scientific thought, aid by public contributions, working cooperatively with his Government and with private enterprise, to produce a great result.

The story from this point of view really begins in 1953. I believe the chairman of this committee at its last session quoted testimony by Dr. Haas before this committee concerning our research interest and a possible poliomyelitis vaccine at that time. Our Laboratory of Biologics Control, which, as its name indicates, has in it the control of these products, is located as a division of the National Microbiological Institute, which is 1 of the 7 institutes comprising the National Institutes of Health. This is the only division of the National Institutes of Health that has any function that is not directly related to medical research. In this control division, they also do research, looking toward the development of new products, new standards, and work of that kind.

It was apparent in 1953 to many scientists familiar with the developments of Dr. Salk's experiments at that time, that they might well result in a suitable vaccine at some future time. From that time through 1953, 1954, and 1955, there is a long series of events which gradually led to this vaccine being a licensed product.

It was on the 17th of July in 1953 that the Chief of Biologics Control visited the Connaught Laboratories in Toronto in order to discuss the growth of poliomyelitis virus on tissue culture at the request of the National Foundation for Infantile Paralysis The specifications for the product to be used by the manufacturers in producing a vaccine for the field trials were drawn up in December of 1953 by the Chief of the Biologics Control Laboratory and by Dr. Joseph Smadel, an eminent virologist at the Walter Reed Army Medical Center. The information

on which these standards were developed was obtained both from the Connaught Laboratories and from Dr. Salk himself.

In January 1954, testing of this vaccine was begun in the laboratory of Biologics Control at the National Institute of Health, after the technicians had visited Dr. Salk's laboratory and had gotten the latest information. At that time, tests were also performed in Dr. Salk's laboratory and by the manufacturer of the product, so that we had triplicate testing in 3 different laboratories for the purpose of enabling these laboratories to develop independently their capabilities and to compare the results between the 3 laboratories for uniformity.

During the period of March 26 to March 28, 1954, the whole procedure, the whole proposition of doing the field trials during the summer, as Dr. Salk had proposed with the support of the Foundation for Infantile Paralysis, was intensively examined. There had been some recoveries of virus from some supposedly inactivated and processed vaccine, and the staff of the Biologics Control Laboratory was concerned about the possibility of producing a safe vaccine on a large scale. As a result of these discussions which were held with Dr. Salk, the foundation's vaccine advisory committee, and the NIH staff, it was decided that additional trials on volunteers should be carried out. The manufacturers' technical directors attended these conferences and helped to evaluate all of the experience up to that date. These field trials were conducted, and the results were presented at a meeting on April 24, 1954. This was attended by the same group that had participated in the discussions in March. All the considerations of all of the field and laboratory experience led to the decision to start the large field trials.

The first draft of the requirements for the production of poliomyelitis vaccine was issued by the laboratory of Biologics Control on May 20, 1954, and this was based on those provisional requirements which I mentioned previously. There was a series of meetings between September and December of 1954 which were held to consider the experience that had been obtained through using merthiolate, which had been used as a preservative in the vaccine, and which had been found to cause loss of potency of the vaccine in some instances. These discussions resulted in the manufacturers conducting some clinical trials of the vaccine without merthiolate, or with merthiolate and another substance called versene, which was added to offset the damage caused by merthiolate, to show that the product without the merthiolate, was comparable in safety to the original product. These clinical trials were carried out successfully.

The results of the foundation field trials conducted in 1954 were presented at the meeting in Ann Arbor on April 12, this year, by Dr. Thomas Francis. This is the report which is now published, familiar to everyone, which indicates that the vaccine that was used during the summer of 1954 on more than 450,000 children in 44 States had been safe and was from 60 to 90 percent effective in preventing paralytic poliomyelitis.

Prior to this meeting in Ann Arbor on April 12, 1955, arrangements had been made for an ad hoc advisory group of eminent scientists to meet with the Chief of the Laboratory of Biologics Control in Ann Arbor immediately after the Francis report in order to decide on the advisability of licensing the vaccine. This group was made

up of Dr. Thomas Turner, of Johns Hopkins; Dr. Joseph Smadel, of Walter Reed; Dr. Howard Shaughnessey, of the Illinois State Health Department; Dr. Albert Sabin, Children's Hospital, Cincinnati; Dr. John Paul, of Yale; Dr. W. McD. Hammon, of the University of Pittsburgh; and Dr. Karl Habel, of the National Institutes of Health. Also present were Dr. David Price, Assistant Surgeon General, United States Public Health Service, and Dr. Victor Haas, the Director of the National Microbiological Institute. This advisory group unanimously recommended that the vaccine be licensed, and by prearrangement the Chief of the Laboratory of Biologics Control in turn so recommended by phone to the Surgeon General, and the Secretary then issued the product licenses to the six firms whose applications were already pending. The revised draft of the minimum requirements went into effect, and release of the lots of vaccine was announced.

That brings us up to April 12.

The first intimation that there was any trouble came on April 26, when the Laboratory of Biologics Control at the NIH received word that there had been 5 cases of polio in children who had received vaccine some 10 or 11 days previous to the report. All had received vaccine produced by one firm, the Cutter Laboratories. Paralysis had begun in each case in the extremity where the vaccine had been injected. Four cases were in California, one was in Chicago, and a sixth case was added during the night. This development led to an all-night meeting at the National Institutes of Health. Telephone checks were made with the California health authorities to establish the authenticity of the cases, and their association with the vaccine. The incidence of polio in nonvaccinated individuals was ascertained and the expectancies were estimated. It seemed likely, though not immediately provable, that the cases were significantly associated with vaccination.

The Surgeon General was kept advised and at 3 o'clock in the morning he decided that additional scientific opinion should be solicited as early as possible in the morning. A telephone conference was set up with Dr. Thomas Francis, Dr. Howard Shaughnessey, Dr. Joseph Smadel, Dr. William Hammon, and members of the NIH staff. The advisers agreed that some action should be taken, but were in agreement that it should be limited to the Cutter vaccine. They did not believe that there was any justification for terminating all polio vaccination.

The Surgeon General acted upon this advice, and at his request the Cutter Laboratories recalled all of their vaccine.

I may say that the telegram went out at 10 o'clock in the morning, and by 10:38 a. m., the Cutter Laboratories had contacted all of their distributors and the next day we had a scientist in the Cutter plant checking on the return of the vaccine.

This left the Public Health Service with two problems which required immediate answers. One, was Cutter vaccine responsible for the occurrence of the cases; and, if so, did this mean that the vaccine contained infective virus, or that the provocation phenomenon was the basis for the development of paralysis in children who happened to be already harboring live virus? And, two, was vaccine from other manufacturers likely to show the same sort of association seen with the Cutter vaccine?

These problems were interrelated in a most complicated way. If they were answered in one manner, the national immunization program would have to be called off. If another, it would go on. This decision in regard to the continuation of vaccination involved appalling considerations. If vaccine was unsafe in general, we could expect many more cases of polio, because by then millions of children would have been vaccinated. If it was safe, it would be regrettable if hasty action were to deprive susceptible children of the vaccines protection. Was the incident, then, coincidence, was it provocation, or was it infection by the vaccine?

While these questions could not be answered immediately, steps had to be taken immediately, and certain assumptions had to be made. The first thing that had to be done was to set up—which Dr. Scheele immediately did on the 28th—a poliomyelitis surveillance unit, to get the epidemiological evidence. What I mean by "epidemiological evidence" is that this is the kind of data that you collect whenever an incident of this kind occurs, as to what people are affected, and where they are affected. If I might cite an example, suppose there was a convention in a big city and an outbreak of illness occurred. You might find on examination that it occurred only in people attending the convention. Then as you examined it further, you might find it was only the people in one hotel. As you examined it further, you might find that this was limited to people who ate at 1 meal at 1 table. You would then draw some inferences that it was something that happened at that table that may have caused the outbreak of disease.

That is the kind of thing we mean by "epidemiological data." This had to be set up, because we had to know the extent of the incident and all of this other data necessary.

On the night of the 27th, we dispatched two scientists to the Cutter plant to begin an intensive investigation of everything in the Cutter plant, which began on the 28th of April, and continued until about the 12th of May. In addition to these 2 scientists, 1 of them a prominent virologist, a sanitary engineer from the Public Health Service was assigned there to look into such matters as airflow, piping, ventilation, and all sorts of engineering problems that might be concerned.

This inspection report is still in process. It has not yet been completed, and we will not be able to report in detail on that until it is completed.

In looking at the problem in the plant, we had to assume that there was an association although we did not have proof of it. If there was something wrong, was it a fault in the normal manufacturing procedure, was it an accidental contamination, or were the manufacturing processes of all manufacturers faulty? This involved the inspection of all the rest of the plants by the same virologist who inspected the Cutter plant. As soon as he finished the Cutter plant, he immediately went to all the rest of the plants, to compare their manufacturing processes with those in the Cutter plant.

Finally, was the method of safety testing sensitive enough to detect a break if it occurred?

These were all of the possibilities that required immediate consideration. I may say that the production of Salk vaccine is an intri-

cate manufacturing process. Whenever you move from a laboratory process to a large-scale manufacturing process, you always run into changes for which you have no previous experience. In making the Salk vaccine, if you overtreat it, you have nothing. It has no potency, no ability to immunize. If you do not treat it quite enough, it may have enough live virus in it to cause paralytic polio. Therefore, you have to operate within a range that is safe within these two extremes, one, complete destruction of its ability to confer immunity, and the other, as much safety as you can put around it so that there is not enough live virus in it to cause disease.

I must point out, too, that in safety testing you can never be absolutely certain in a biological product that the product in one particular vial is absolutely safe, because the only way you could determine that would be to test every drop of stuff in that vial. Then you would not have anything to use. So you set up the best test you can devise to reduce the chances to as near zero as you possibly can, and then you let the product go on the basis of its probability of complete safety. There is no other way to arrive at that. I think we might compare the situation here to a situation that exists, say, when you produce a new commercial airliner. To produce a new commercial airliner, you put into it every bit of engineering brains, every bit of research exeprience you can. You test it as thoroughly as you can before you give it a license of airworthiness. Then you license it, and then perhaps something happens.

Your immediate problem is: Was it human error or did something fail in this great, complex machine?

If you cannot decide, you have to ground all of the planes of that model until you can find what the trouble is.

I think we can cite the British experience with the jet airliner, the Comet. I am told that this was thoroughly tested, that it even had 2 years of actual use before they began to have trouble. When they had trouble, they grounded everyone of those planes until they could thoroughly study the problem, and find out what the trouble was. Now they are building a safer model, I am told, and I have no doubt it will be safer than the original plane.

There are similar safety tests for the polio vaccine. There is a safety test which is supposed to indicate whether live virus got through the period of activation. This involves inoculation into tissue cultures and into monkeys at various stages of processing. These tissue cultures are made of monkey kidneys. The critical point is that if live virus survives in small quantities which may be capable of producing disease in a few individuals out of many thousands injected, the tissue cultures and the monkey assays must be sensitive enough to detect such small quantities if human illness induced by the vaccine is to be prevented.

But the susceptibility of humans has never been measured. Indirect evidence suggests that it is much greater than that of the monkeys used for safety tests. Monkeys have viruses of their own. These come out in tissue culture that are made from monkey kidneys. Thus, if a tissue culture safety test shows evidence of virus, time must be spent to identify this virus to show whether it is polio virus or one of these so-called wild viruses that got in there from the monkey tissue itself.

The committee was able to learn from manufacturers that inactivation (and this was the discussion we had with the manufacturers after the incident) sometimes fails in the plant for no immediately apparent reason. There was evidence also that the safety tests were perhaps less sensitive than was desired. On some occasions, pools of virus, each containing a single type and each negative after inactivation, were combined into what are called polyvalent pools, which then gave positive tests.

Difficulties of this sort had been considered early in 1954 and had been dealt with by attention to manufacturing details and by additional tests on human volunteers. The sequence of successful production lots following these early difficulties and the massive field trial created confidence that, despite the inherent difficulties in manufacturing and testing, a safe product was obtainable.

The committee members now felt that the occurrence of poliomyelitis following the use of the Cutter vaccine lessened this confidence even though we did not know what the trouble was. The supposed margin of safety conferred by inactivation, far beyond the calculated period, appeared no longer to be fully dependable. The sensitivity of te safety test in the light of the manufacturers' experience was less than satisfactory. It appeared, though it was not yet established, that live virus might be surviving even the most rigorous processing and escaping detection in the safety test. At least in some instances, even though relatively few, it might be present in the final product in sufficient quantities to cause illness in some susceptible individuals.

On the basis of this new information, the committee agreed that changes in the minimum requirements should be considered. They felt that inactivation could be more rigidly controlled and safety testing could be improved. They drew up a draft of possible changes, suggesting that industry be asked to study and to comment on them. The committee was careful not to insist on their being adopted until it could be determined that they were likely to be of practical value.

The Surgeon General met with the committee in the closing hours, and after studying their views and the available facts upon which they were based, decided to recommend suspension of the national vaccination program until each manufacturer's records and procedures could be checked by a competent team. Such checks would provide detailed information on all lots, whether or not they had been submitted for release. This would permit closer examination of each producer's consistency in respect to successful inactivation and performance of safety tests. If there were any faulty practices that might have prejudiced certain lots, they could be evaluated before any more vaccine was used.

This plan was carried through. The decision to recommend suspension was announced on May 7. On May 13, there were 11 lots of Parke-Davis vaccine cleared following plant inspection and study of the company's records. The national program again got underway.

On May 15, there were more clearances, three lots of Lilly vaccine and another lot of Parke-Davis. A group of consultants met with the NIH staff members on May 15 to consider information obtained from the Cutter inspection and from those made at Parke-Davis and Lilly. The consultants were Dr. Jonas Salk, Dr. William Hammon, and Dr. Joseph Smadel. This new information indicated that all these plants were having problems in processing that tended to lessen

confidence in the safety of commercially processed vaccine in general.

It seemed to the group, however, that certain lots could be selected on the basis of stricter criteria than had been previously contemplated which would have an appreciable margin of safety. In addition to approving such selected lots, the consultants suggested that a meeting be held with manufacturers on May 23 to discuss all the difficulties that were coming to light as a result of these intensive studies, to see what could be done to increase the safety of the vaccine, and estimate the effect of these more stringent criteria upon the supply of vaccine.

By May 18, the inspection had been completed at the Wyeth plant, and by May 21 the inspection of the Pitman-Moore plant had been finished.

By May 23, when the meeting with the manufacturers was held, all data from the manufacturers was at hand and had been analyzed. All inspections had been completed, except that of Sharp & Dohme, who are not yet producing for the market.

These data were studied, and indicated a lack of sensitivity of the safety test, and this convinced the scientific advisers that even more stringent criteria must be applied both to finished lots, waiting to be assessed for release, and to those still in production or to be produced.

Meanwhile, many samples of Cutter vaccine are being subjected to laboratory tests. This will require more time to complete.

The committee, on May 23, recommended changes in processing controls and in safety tests. These changes are based upon long and intensive accumulation and analysis of facts turned up by a detailed study of the manufacturers' records. They are supportable on the basis of statistical analysis. In one form, they can be applied to vaccine already finished and awaiting release, permitting selection of only the best lots. In another form, they can be applied to all newly produced material, thereby contributing to a built-in margin of safety.

Gentlemen, at 2:15 this morning, we finished a 2-day meeting with the manufacturers, our staff and our panel, and we reached a complete understanding in minute detail as to how the revised standards affect the production and testing processes of each plant. Some vaccine, but not as much as we hoped, is going to be available soon.

That is the story as of this morning.

The CHAIRMAN. Thank you very much, Dr. Sebrell, for bringing us up to date on the story.

Now, Mr. Hinshaw, you may resume your questioning.

Mr. HINSHAW. Mr. Chairman, before I ask questions, I would like to say that certainly I, as one member of this committee, and I am sure the entire committee and the public, appreciates not only the heavy responsibility that lay upon the shoulders of this committee and the National Institutes of Health, but also upon the Surgeon General in making these necessary determinations as between the point of whether we should go forward in the belief and in the hope that immunization would be given to millions of children, or if we should stop in order that none might suffer from this particular material. It is a very close decision. I am sure it must have been hard to make.

The CHAIRMAN. Will the gentleman yield?

Mr. HINSHAW. Yes.

The CHAIRMAN. I was just thinking as Dr. Sebrell recounted receiving the messages of the first five cases, that I certainly would not have

wanted at that moment to have had to make the decision myself, realizing all that was involved. It was a pretty terrific decision to be made at that point.

Mr. HINSHAW. I am sure we are all glad that competent people made the decision.

The CHAIRMAN. I agree with you fully.

Mr. WILLIAMS. Will the gentleman yield to me?

Mr. HINSHAW. Yes.

Mr. WILLIAMS. In my opinion, rather than have the people in responsibility who had to make these decisions charged with mishandling the program, I think they should receive the congratulations and appreciation of everybody in the country for the manner in which they have exercised caution in the handling of this vaccine.

Mr. O'HARA. Will the gentleman yield?

Mr. HINSHAW. Yes.

Mr. O'HARA. I would like to say, Mr. Chairman, that I share the expression of views which my colleagues have expressed, not only to the Department but to the National Institutes of Health and to Dr. Scheele. He had a highly hysterical, emotional situation to deal with, and he also had to make the very definite, scientific decision which had to be based upon facts as near as he could get them. It was an extremely difficult one. Personally, I want to say as one individual member of the committee, I concur completely in the efforts which have been made in the overall interest of safety in this program.

Personally, I want to thank you for what you have done, Doctor.

Mr. HINSHAW. I understand that in the Salk field trials in 1954, 422,743 children received the Salk vaccine. Is that correct?

Dr. SEBRELL. Yes, sir.

Mr. HINSHAW. And that dummy injections were given to an additional 201,229? I think you called them placebos?

Dr. SEBRELL. Yes. That was a control group. The placebos had no effect in immunizing the children.

Mr. HINSHAW. And during the field trial vaccination period, 90 cases of polio symptoms were reported among those who received the vaccine, is that correct?

Dr. SEBRELL. There were 90 reported cases of poliomyelitis among the entire study population—vaccinated and controls.

Mr. HINSHAW. And in the following 2 weeks 39 more showed up, thus making a total of 129 cases of presumed polio between May 1, 1954, and 4 weeks later?

Dr. SEBRELL. That is correct, sir, for the entire study group.

Mr. HINSHAW. In the course of those trials, was any Cutter vaccine used?

Dr. SEBRELL. No Cutter vaccine was used in those trials. The Cutter laboratory had prepared vaccine for the trials. It had been tested in the triplicate testing and it had passed. But because it was not needed, the Cutter vaccine was not actually used in the trial.

Mr. HINSHAW. In the observed areas, 76 vaccinated children were reported as showing polio symptoms, but of these, 56 cases only turned out to be polio, or in the ratio of 25 per 100,000.

Dr. SEBRELL. Yes.

Mr. HINSHAW. And in the areas of dummy injection, 82 who had received the dummy vaccination were reported as showing polio symp-

toms, and of these, 57 cases were polio or 28 per 100,000, is that correct?

Dr. SEBRELL. That is correct.

Mr. HINSHAW. Then, finally, upon analysis, the first 90 cases were excluded from later evaluation?

Dr. SEBRELL. I believe that is correct.

Mr. HINSHAW. May I inquire why the 90 cases were excluded?

Dr. SEBRELL. Well, you understand, sir, that this is Dr. Francis' report and these exclusions were based on the criteria they were using in the study. I am not sufficiently familiar with the rules he used, or the logic he used, in including or excluding cases to testify as to all the reasons why they were not included. Perhaps Dr. Scheele can add something.

Dr. SCHEELE. Without rereading a portion of the report, I cannot answer the question specifically, but I can mention some of the kinds of things that lead to exclusion. There were some children who received only one injection, and they were excluded. There were other children who received injections of material that were found not to have high potency in producing antibodies. It obviously would be unfair to include such a case in the grouping of cases that came through properly with inoculated children. There were factors of that sort that led to these exclusions, and I think they were appropriate exclusions to make.

Mr. HINSHAW. I understand in the test area, 303,201 persons were not inoculated and that 157 cases of diagnosed polio were reported out of this total or, I believe, it was three times the rate of incidence of those who were inoculated. In other words, approximately 50 per 100,000.

Dr. SEBRELL. I believe that is correct.

Mr. HINSHAW. I believe that was the Francis report of April 12, 1955, that encouraged the committee to think that we should go ahead at the earliest possible date in not only the production but the use of this vaccine.

Dr. SEBRELL. That is correct, sir, because the vaccine in the 400,000 children demonstrated that it was potent, that it would produce a degree of immunity, and antibodies were also created, which are a measure of immunity, and at the same time it provided, incidentally, an additional test of the safety of the product.

Mr. HINSHAW. In other words, that reduction in the incidence of polio among those who were vaccinated, who received the vaccine, would indicate that if the vaccine were widely used, that far fewer children, certainly, would be subjected to the incidence of this disease?

Dr. SEBRELL. That is certainly correct. I don't believe anyone has ever said that this is a perfect vaccine. We have been very careful not to say that. It will not give 100 percent protection based on this evidence. But it gives enough protection so that it is certainly going to prevent polio in some children, if we can believe the data that Dr. Francis presented. I have great confidence in him. He is an eminent scientist. He had an eminent group of people working with him, including statisticians. I feel we can place confidence in this report of Dr. Francis.

Mr. HINSHAW. And it was that fact which led the Department to think that it should ask the Congress for the passage of this bill, H. R. 6286, in order to make sure that all of those children who would other-

wise want to be vaccinated, or their parents would want to have them vaccinated, would receive the vaccine regardless of their circumstances in life?

Mr. PERKINS. That is correct, sir.

Mr. HINSHAW. That is the reason why we have this bill before us?

Mr. PERKINS. Yes, sir.

Mr. HINSHAW. The hearings, therefore, become 2 or 3 bladed, so to speak: First, to impress Congress as the representatives of the public that the vaccine is relatively safe and does produce immunity among a very large percentage of the children; and, next, that we should, through some bill such as this, make provision for all children to have it.

Mr. PERKINS. That is correct.

Mr. HINSHAW. And this would be a public health measure and in the interest of the public health.

Mr. PERKINS. Yes, sir.

Mr. HINSHAW. Now I would like to direct my questioning to some things which were brought out in the course of the testimony the other day. The question was asked whether any other of these six laboratories had even been charged with a fault. Is that answer available?

Mr. PERKINS. Yes, sir; we have the data and would be pleased to submit it for the record, if that is the wish of the committee.

Mr. HINSHAW. Mr. Chairman, that looks to be a fairly voluminous document. I would suggest that the staff examine it and perhaps concentrate its information so that we may know what it is.

The CHAIRMAN. The Chair feels that that is perhaps better than making it a part of the record, since it does appear to be quite bulky and no doubt can be condensed and digested for the information of the committee.

Mr. WILLIAMS. Does that cover all six?

Mr. HINSHAW. That covers all six manufacturers of the Salk vaccine, does it not?

Mr. PERKINS. Yes, sir.

Mr. HINSHAW. And seizures have occurred in every instance?

Mr. PERKINS. It is my understanding that there have been seizures——

Mr. HINSHAW. In every company?

Mr. PERKINS. Dr. Larrick, would you answer that?

Dr. LARRICK. All of them had seizures. There was only one case where the information was filed.

Mr. HINSHAW. One case where infomration was filed, but all of them had cases of seizures of their material?

Dr. LARRICK. That is right, over the time of 14 years.

(The summary of the information requested is as follows:)

JUNE 1, 1955.

Upon the request of the House Committee on Interstate and Foreign Commerce the Food and Drug Administration has prepared the attached summary of the legal actions instituted under the Federal Food, Drug, and Cosmetic Act against drugs manufactured by the following firms now making the Salk vaccine:

(1) Cutter Laboratories, Inc., Berkeley, Calif.
(2) Eli Lilly & Co., Indianapolis, Ind.
(3) Parke, Davis & Co., Detroit, Mich.
(4) Pitman-Moore Co., Indianapolis, Ind.
(5) Sharp & Dohme, Inc., Philadelphia, Pa.
(6) Wyeth Laboratories, Philadelphia, Pa.

The Notices of Judgment upon which this summary is based were previously submitted to the committee; the footnotes in this summary refer to those publications.

(1) CUTTER LABORATORIES, INC., BERKELEY, CALIF.

In 1942 a shipment of distilled water intended for injection purposes was seized under allegations that it was not safe for injection because it contained pyrogens; that is, foreign substances which produce fever.[1]

Between 1943 and 1946, 20 seizure actions were instituted against various drugs intended for injection. These drugs were all solutions which failed to meet the then existing requirements of the United States Pharmacopoeia because they were not sufficiently clear and free from turbidity or undissolved particles. Subsequently the United States Pharmacopoeia has dropped the requirements as being impractical. The manufacturer did not contest any of these actions; the courts condemned the articles and ordered their destruction.[2]

In 1949 the corporation was prosecuted for shipping dextrose and sodium chloride injection and Ringer's solution. The drugs were alleged to be unsterile and, therefore, unsuitable for injection because they would be dangerous to health. The charges involved shipment from California into five other States. The corporation entered a plea of nolo contendre and was fined $600.[3]

(2) ELI LILLY & CO., INDIANAPOLIS, IND.

In 1941 a shipment of tincture of digitalis was seized because, it was alleged, its potency was only about 63 percent of the minimum allowed by the United States Pharmacopoeia. No one claimed the article, so the court condemned it and ordered its destruction.[4]

In 1945 a drug intended for injection was seized under the allegation that it was not free from undissolved material as required by the National Formulary at that time. (Since then, the requirement has been dropped by that official compendium as being impractical.)

The manufacturer appeared in court as claimant and consented to a decree of destruction provided the record would show that the undissolved material was the result of a disintegration of the drug which probably occurred after completion of the manufacturing process.[5]

In 1953 four articles were seized. Three of them, acetylsalicylic acid tablets, potassium iodide tablets, and rhinitis tablets were alleged to be misbranded in that their labelings did not bear adequate directions for using them. In addition the name "Tablets Rhinitis" was alleged to be false and misleading because the drug was not an adequate and effective remedy for rhinitis. The fourth article, ophthalmic ointment, was seized under the allegation that it was a drug which should be restricted to dispensing only on prescription and the label failed to bear a legend stating that fact as required by the law. No claimant appeared; a default decree of condemnation and destruction was entered.[6]

(3) PARKE, DAVIS & CO., DETROIT, MICH.

In 1941 a shipment of fish livers (a crude drug) was charged to consist in part of a filthy substance. The company appeared as claimant, consented to a decree of condemnation and salvaged the good portion of the lot.[7]

In 1941 a proprietary preparation (consisting of acetanilid, aspirin, and caffeine) made by Parke, Davis & Co. for another concern was seized under allegations that it was misbranded because of certain statements appearing on the bulk tablets as shipped by this company and in the labeling applied by the distributor. The bulk tablets failed to bear adequate directions and warnings and the label did not use the common name, "aspirin," in the statement of active ingredients. The seizure went by default and the drug was destroyed.[8]

In 1942 two shipments of epinephrine tablets for hypodermic use were seized under charges they were subpotent. One lot went by default, the company claimed the other for salvaging.[9]

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[1] Notice of Judgment 978.
[2] Notice of Judgment 1113, 1372, 1375, 1423, 1424, 1612, 1712, 1973.
[3] Notice of Judgment 2851.
[4] Notice of Judgment 466.
[5] Notice of Judgment 1715.
[6] Notice of Judgment 4021.
[7] Notice of Judgment 560.
[8] Notice of Judgment 601.
[9] Notice of Judgment 761.

A shipment of pituitary solution posterior lobe was seized in 1942. It was alleged to be more physiologically active than the maximum potency permitted by the United States Pharmacopoeia standard. No claimant appeared; the court condemned the drug and order its destruction.

In 1943 a shipment of ampuls of chloroform for anesthesia was seized under charges that the acid content of the drug exceeded the maximum allowed by the United States Pharmacopoeia standard. The company claimed the goods and the court released the chloroform but provided a restriction that it not be used for anesthesia.[10]

In 1944 a shipment of bandage compresses was seized. It was alleged they were not sterile as stated by the label. The company claimed the goods and received the bandages for resterilization under supervision. A similar seizure was made in 1945.[11]

In 1944 a shipment of digitalis preparation was charged to be adulterated and misbranded because it differed in potency from the standard United States Pharmacopoeia article.[12]

In 1944 various crude drugs in the possession of the company in Detroit were seized because they contained filthy substances and/or had been held under insanitary conditions. Inspection of the premises had revealed poor storage facilities resulting in contamination by rats and insects.

The company admitted the allegations of the libel and salvaged portions of the drugs.[13]

Thyroid tablets of various sizes were seized in 1945 because each size was alleged to contain 1½ times the amount of thyroid declared on the labels. The tablets were released under bond to be brought into compliance.[14]

In 1946 a shipment of theelin in oil was seized because its potency was greater than the label stated it to be. The company consented to the decree and received the article to be brought into compliance under supervision.[15]

In 1950 an herbal preparation was seized under the allegation that the label did not bear directions for using it. A default decree was entered and the drug was destroyed.[16]

(4) Pitman-Moore Co., Indianapolis, Ind.

In 1946 a drug was seized because the label represented that it was effective for the treatment and prevention of certain animal diseases. It was alleged the article was ineffective for those diseases and the company accepted a consent decree providing for relabeling.[17]

In 1947 two shipments of sodium chloride solution for injection were seized because, it was alleged, the solution contained undissolved particles and therefore did not meet the then existing United States Pharmacopoeia standard. (Since that time this requirement has been dropped by the United States Pharmacopoeia as being impractical.) A default decree of destruction issued. A seizure of sodium sulfadiazine solution was made on similar charges in 1948.[18]

Four seizures of an estrogenic (female hormone) drug were made in 1951. The label claimed that each cubic centimeter of the solution contained 2 milligrams of active ingredient but, it was alleged that the lots sampled contained less than that amount, namely, 1.18 milligrams, 1.52 milligrams, 1.64 milligrams, and 1.42 milligrams.[19] One seizure terminated in a default decree and destruction of the drugs; the other three were settled by consent decrees providing for relabeling.

(5) Sharp & Dohme, Philadelphia, Pa.

In 1939 two preparations of digitalis were seized under allegations the drugs were subpotent because one preparation contained only two-thirds the claimed amount, the other only two-fifths. A default decree was entered and the drugs destroyed.[20]

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[10] Notice of Judgment 1219.
[11] Notice of Judgment 1289, Notice of Judgment 1823.
[12] Notice of Judgment 1470.
[13] Notice of Judgment 1569.
[14] Notice of Judgment 1673.
[15] Notice of Judgment 2166.
[16] Notice of Judgment 3268.
[17] Notice of Judgment 1944.
[18] Notice of Judgments 2369, 2738.
[19] Notice of Judgments 3513, 3611, 3629, 3672.
[20] Notice of Judgment 87.

In 1949 a shipment of a preparation of "laxative cold tablets" made by this company for another concern was seized. It was alleged the tablets were misbranded by the labels on the manufacturer's bulk material and on the packages filled from it by the distributor. The bulk tablets failed to bear adequate directions, adequate warnings, and the common or usual name for each of the ingredients. The distributor claimed the goods, accepted a consent decree providing for relabeling.[21]

In 1941 a lot of "water for injection" was seized on charges that it contained living mold and was not sterile. Seizure terminated with a default decree and destruction.[22]

In 1945 four lots of "water for injection" were seized because the drug failed to meet the then existing United States Pharmacopoeia requirement on undissolved particles. (Since then the United States Pharmacopoeia has dropped the requirement as impractical.) The company did not appear as claimant, and the drugs were destroyed.[23]

(6) WYETH LABORATORIES, PHILADELPHIA, PA.

In 1944 and 1946 three lots of various drugs for injection were seized under charges the articles failed to meet the then existing United States Pharmacopoeia requirement on excessive amounts of undissolved particles. (Since then the United States Pharmacopoeia has dropped the requirement as being impractical.) All seizures terminated in default decrees and destruction of the drugs.[24]

Mr. HINSHAW. Is the case of seizure subject to an information filing if you chose to do so?

Dr. LARRICK. Yes.

Mr. HINSHAW. So any degree of liability for a mistake is approximately equal among the six?

Dr. LARRICK. Under the pure food and drug law, there are circumstances where a project can be shipped in interstate commerce and be 100 percent all right. But if it got spoiled or deteriorated, then it would be subject to seizure. Some of these cases involved that sort of action. But under this law, every case that is filed with the Federal court and terminated has to be reported in a published document. So we have compiled here the published documents, the public information. It explains each one of those actions since this law was passed in 1938.

Mr. HINSHAW. I understand there are 10 firms in the United States who were adjudged competent to produce this vaccine.

Am I correct?

Dr. LARRICK. That would not be in my field. I believe Dr. Sebrell or Dr. Scheele can answer that.

Dr. SCHEELE. The National Foundation for Infantile Paralysis went to approximately 10 manufacturers who appeared to be competent to make the vaccine, to see if they would be interested in attempting to produce materials for a field trial and later for the broader program if the vaccine were good. Six of them were interested in making it. In fact, they were willing to prepare to do this job.

Mr. HINSHAW. And all six were, to that extent, volunteers?

Dr. SCHEELE. That is correct.

Mr. HINSHAW. They all were first asked to do it, and then six of them volunteered?

Dr. SCHEELE. That is correct, sir.

Mr. HINSHAW. I do not see how any particular amount of political pressure that was ascribed to this thing the other day could have

[21] Notice of Judgment 659.
[22] Notice of Judgment 1521.
[23] Notice of Judgments 1611, 1770.
[24] Notice of Judgments 1421, 1573, 2025.

possibly been brought under such conditions, having been invited and having accepted the invitation to produce the material.

Mr. PERKINS. I assure you there was none, sir.

Mr. WILLIAMS. Will the gentleman yield?

Mr. HINSHAW. Yes, sir.

Mr. WILLIAMS. Was Cutter Laboratories approached and invited, or did they come into the program on the basis of their own request?

Dr. SCHEELE. I would probably have to ask the National Foundation for Infantile Paralysis for an exact statement on that. It is my impression they were invited. They did produce three production lots of vaccine for the field trial, but because the total number of children was reduced from the earlier plan, which might have included 2 million or so, and because the season was coming on, their materials were not used, and it was decided to use the materials from Parke-Davis and Lilly in order to have uniformity of materials used.

Mr. HINSHAW. But it was the National Foundation for Infantile Paralysis that sought out these manufacturers and not the Government agency; is that correct?

Dr. SCHEELE. That is correct, sir; yes, sir.

Mr. HINSHAW. I think that settles the case permanently, as far as I am concerned. If there is any further questioning, I would be glad to yield to my friends on the committee.

Mr. HARRIS. Will the gentleman yield?

Mr. HINSHAW. Yes, sir.

Mr. HARRIS. Did I observe that Mr. O'Connor, of the foundation, made some statement in which he inferred that there had been some—I would like to defer, Mr. Chairman, to observe the appearance of Secretary of Health, Education, and Welfare.

The CHAIRMAN. The Chair feels it is highly in order to defer to recognize the presence of the Secretary.

We welcome you, Mrs. Hobby. We are very happy to have you before the committee. I think if you have any statement that you want to make to the committee at this time, we would defer any further questioning until you made such a statement.

Secretary HOBBY. Mr. Chairman, I have no prepared statement. I wish to apologize to the Chair and to the members of the committee for not being here when you opened. Some weeks ago there was set on the Cabinet agenda the briefing of the White House Conference on Education. The chairman of that committee had come from out of town to do that, and I had to present it. I have no prepared statement, Mr. Chairman, except to thank you and the members of this committee for the way you have approached a problem that concerns this committee, the Members of Congress, the Department, and the American people so inimately.

Thank you.

The CHAIRMAN. Thank you very much, Mrs. Hobby.

You may proceed, Mr. Harris.

Mr. HARRIS. Thank you, Mr. Chairman. I asked the gentleman from California to yield in view of the statement that had been made. But then I wanted to take this occasion to welcome the Secretary here, and say that we hope that her husband is feeling much better.

Secretary HOBBY. Thank you very much.

Mr. HARRIS. I did not hear of the report referred to yesterday until it was mentioned here in this committee. I did not know the source

of it, and certainly did not have any information as to its authenticity. I did hear, since then, after making some inquiry, that the matter arose out of a statement which Mr. Basil O'Connor made, inferring in the statement, as I understood, that there had been some political interference.

Do you know of any such reports or anything that might have appeared in the newspapers where such inference could have been made?

Dr. SCHEELE. Mr. Harirs, I do not know of anything that has happened anywhere along the line on the scientific side of this problem, the licensing, the study of the problem of the vaccinated children who developed polio, or any of the things that have happened that could be called politics.

Mr. HARRIS. Yes, but I thought what Mr. Hinshaw was endeavoring to clear up was the statement that was made. I do feel that if some statement, unfortunate statement, was made which had implications for anyone, regardless of who it might be, the record should show that it had come from a particular source that would be responsible for it. If Mr. Basil O'Connor did make such a statement in some report or a news report, or the newspapers did carry such an inference that he made it, it is my understanding that that was the basis for the questions Mr. Klein asked yesterday, and I do say that in order that Mr. Hinshaw, being from California, might know the information I received after making some inquiry.

Certainly I would be the first one to say that no such implication could possibly be directed at Mr. Hinshaw, the distinguished member of this committee. And I would want him to know that.

Mr. HINSHAW. Thank you. But I think the matter ought to be cleared up completely. There is no sense in having any slight odor surrounding any such thing as important as this. I believe that if Mr. O'Connor made such a statement, he should be inquired of concerning his sources of information.

Mr. HARRIS. I want to make it perfectly clear that I do not know that Mr. O'Connor did or not. But inquiring as to the source that prompted the question yesterday, I understood that it came from an inference that he had made in a public statement. I have joined the gentleman in saying that the political intercessions have no place whatever in this, because it is too important to the American people and the future welfare of our children.

Mr. WILLIAMS. May I say at that point, Mr. Chairman, that I attempted to get to the bottom of the rumors on which Mr. Klein based his questions. The best that I could find out was that it arose from an interpretation put on Mr. Basil O'Connor's words by a certain newspaper columnist here in Washington. So far as this is concerned, I am fully convinced it has no basis in fact whatsoever.

The CHAIRMAN. Is there anything further?

Secretary HOBBY. Mr. Chairman?

The CHAIRMAN. Mrs. Hobby, do you wish to make a statement this morning?

Secretary HOBBY. May I, to the Chair and to the members of this committee, make a statement in reference to the question which was asked by Mr. Klein, I believe, yesterday.

I would like, at this time, for the benefit of the Chairman and the members of this committee, who for the past 30 months I have always

found to be so fair and so sympathetic to what the Department has been trying to accomplish for the American people, to make this simple statement. I can speak unreservedly for myself and I believe equally so for every person in the Department of Health, Education, and Welfare. There has been no politics in this. No person ever has attempted to bring undue political pressure on me at any time in the 30 months I have been in this job. To be more specific, Mr. Chairman, no one other than the Surgeon General of the United States, whose duty it is under the law to recommend to the Secretary of Health, Education, and Welfare the manufacturers who should be licensed, ever mentioned any manufacturer to the Secretary of Health, Education, and Welfare.

Mr. HARRIS. Mr. Chairman?

The CHAIRMAN. Mr. Harris?

Mr. HARRIS. I am very glad to hear the statement from the Secretary and it is very encouraging. But I do believe I would be justified in saying this in the absence of Mr. Klein. He certainly needs no one to defend him for anything he asked. But I think the record should show, in view of the fact that the question has been brought up again, that Mr. Klein asked a question, as I was advised by him, which came out of a conversation that another Member of the Congress had with him, who suggested that such a question be asked of someone from the Department. I think in all fairness to Mr. Klein that statement should be made.

Secretary HOBBY. Mr. Chairman, if I gave any misinterpretation—I believe so firmly and so deeply in the American system of government as it operates, and in the sovereignty of the people who elect you gentlemen to come here and represent them in the Halls of Congress, that I would never at any time have any hesitation to answer any question ever addressed by a Member of the Congress.

Mr. MACDONALD. Mr. Chairman, on that, I believe Mr. Klein just did not make that inquiry on the basis of a conversation with a single Member of Congress. I believe Mr. Klein in his very fair way wanted to give the Department an opportunity to deny this very well-spread and long-time rumor. I do not believe it was confined to just two Members of Congress. I know I have heard it myself, and I have heard it very often. I think it was just because of a sense of fairness that Mr. Klein wanted to give the Department an opportunity to deny it.

Secretary HOBBY. Thank you.

The CHAIRMAN. May the Chair state also that in conversations with Mr. Klein and others, the Chair is inclined toward the view expressed by Mr. Macdonald that it was asked simply because there had been rumors spread. I think Mr. Klein in asking the question was simply attempting to bring out a rumor that had spread around, and that I think was started primarily, as Mr. Harris suggested, on the basis of a misinterpretation or an interpretation of something Mr. O'Connor had said, in a wire to the Surgeon General. As I recall, I think possibly it grew out of an interpretation of a wire concerning a report from the Department on the Cutter investigation.

But, nevertheless, I think that that was probably the basis of the item. The Chair is glad that we have had this opportunity to hear directly from the Secretary on this matter. The Chair feels that it is cleared entirely.

Secretary HOBBY. Thank you.

The CHAIRMAN. Mr. Hinshaw, do you have other questions?

Mr. HINSHAW. Yes. I wish to bring into the record at this point a study which has been made on this subject and the Francis report. I believe the figures come from the Francis report.

The CHAIRMAN. Yes, that is correct.

Mr. HINSHAW. I would like to point out a very curious fact. Of the cases of paralytic polio, per 100,000, 16 per 100,000 received vaccination; 57 per 100,000 had the dummy vaccination, and 36 per 100,000 had no inoculation whatever. That would indicate something which I do not understand. That is that those who received no inoculation had a far less incidence of paralytic polio than those that received the dummy vaccination. Can anyone explain that?

Dr. SEBRELL. There are several possible explanations for that, I think. I should not try to answer this specifically because this is Dr. Francis' data, and he and his staff should answer it directly. But I can make some inferences.

The reason for using the placebo, the dummy vaccination, was to have as nearly as possible a directly comparable group of children with those vaccinated, because the uninoculated children, or merely children in the same areas in which the vaccine was given, were not an adequate control. Therefore, you are not justified in drawing a direct inference between vaccinated and nonvaccinated children. The direct inference must be drawn between vaccinated children and placebo children, because while the nonvaccinated children in other areas constitutes some evidence, it is not conclusive because you do not know what their exact duplicates would have had if they were vaccinated.

That was the reason for running the placebo group. No one wanted to deny the values of vaccination. But this was the only way in which you would get a comparable group with the unknown incidence of polio occurring all the time and varying in different places and different years and different seasons. This is the only really truly comparable group.

Mr. HINSHAW. We are not particularly concerned about the nonparalytic cases, because I suppose many have had nonparalytic poliomyelitis and not even known it.

Dr. SEBRELL. That is probably correct.

Mr. HINSHAW. The incidence of nonparalytic cases per 100,000 seems to be about the same between those vaccinated and those not receiving the vaccination which is an interesting fact, although it is a small number, 12 per 100,000 and 13 per 100,000 of the placebo, and 11 per 100,000 for the nonvaccinated.

Dr. SEBRELL. At best, Mr. Hinshaw, the diagnosis of nonparalytic polio is a very difficult diagnosis. It is a rather vague illness, and since it does not leave any permanent damage it is all over in a relatively short period of time. We know that there are still many vague conditions from which children suffer which we do not know the cause of, which could possibly be confused with this group. So everyone is very careful in trying to analyze data on nonparalytic polio even under the best conditions. In order to make an exact diagnosis, you must recover the virus, recover and identify the virus, or show an increase in antibodies, in order to be sure that that is the disease. In many instances virus isolation is done, of course, but that is a rather time-consuming

and laborious laboratory procedure and not too many people are equipped to do it.

Mr. HINSHAW. It is stated here that on each lot of vaccine which is produced, it is necessary to inject 30 rhesus monkeys, or 30 monkeys, as a test measure. Has that been changed by your agreement of last night?

Dr. SEBRELL. No; the monkey test was not changed last night. This involves the use of at least 18 monkeys that are used on each lot for the purpose of determining whether they will get polio, and an additional 12 monkeys that are used for a potency test. That is being continued just as it was.

Mr. HINSHAW. I think I will suspend in order to give other members a chance to question. But after they have completed, Mr. Chairman, I have some other questions.

The CHAIRMAN. Mr. Carlyle?

Mr. CARLYLE. No questions.

The CHAIRMAN. Mr. Beamer?

Mr. BEAMER. Mr. Chairman, I regret very much that I was called out of the committee room. I know I missed some very important statements this morning. However, I would like to continue on some of the other remarks, and also on the statements given to the committee the other day. I do have a question or two.

I would like to take this opportunity, however, to extend to my fellow Hoosier, Dr. Scheele, congratulations on a job well done, and that includes the entire group which has been working with this very important problem.

I want to compliment you, if I may take the time, on carrying this above any political level that some other people apparently attempted to make it. This matter is purely professional, and I think that is very desirable.

There are only 1 or 2 questions in which I am interested. I think you have referred to the fact that there is an incidence, shall we say, of bad results or unfavorable results coming. I am wondering how many vaccines besides the polio vaccine would be included under paragraph A in the bill itself.

Mr. PERKINS. How many what, Mr. Beamer?

Mr. BEAMER. The statement was made, as I remember it, that—I am referring to H. R. 6207.

Mr. PERKINS. I see it. In section A, in other words, you are referring to the provisions of existing law in the Biologics Control Act.

Mr. BEAMER. That is right. How many vaccines or similar treatments would be coming under that provision in addition to polio? I presume there are quite a number.

Mr. PERKINS. In other words, the question, I take it that you are asking Dr. Sebrell, is how many types of vaccines do they license under the provisions of subsection A.

Mr. BEAMER. Subsection A under section 351.

Mr. PERKINS. And of the Public Health Service Act.

Mr. BEAMER. That is right.

Dr. SEBRELL. Mr. Beamer, there are currently in excess of 200 products under license.

Mr. BEAMER. And those have been licensed over a period of years?

Dr. SEBRELL. Yes. Some of them for many years.

Mr. BEAMER. I am interested in knowing over that period of time what the results were that were produced when you first started to license other vaccines. Have you any history of that? Can you cite only a few instances, perhaps?

Dr. SEBRELL. I might cite you one instance that led to the enactment of the original act in 1902. The reason we have a Biologics Control Act is that in the year 1900 or 1901 some diphtheria antitoxin was produced, which was inoculated into children and killed them from tetanus. It was this tragic happening that led to the enactment of the original Biologics Control Act.

Mr. BEAMER. And since that time, when certain products have been manufactured by certain biologics laboratories, have we had any comparable experiences?

Dr. SEBRELL. I do not recall that we have had any serious one with a licensed product since the act has been enforced in the past fifty-odd years. There has occasionally been trouble with products, since difficulties develop as processes are changed, but nothing of the tragic type of thing that this incident represented.

Mr. BEAMER. I was wondering whether this was uncommon or common.

Dr. SEBRELL. Very rare. There are such incidents in other parts of the world. These things occur not only in this country but everywhere. All biological products are potentially dangerous. As I indicated, you cannot prove with certainty that the final product is absolutely sterile. There was a famous incident in trying to develop a vaccine for tuberculosis, the BCG vaccine, in which a mistake of some kind was made. The wrong culture was developed and several children in a foreign country were given tuberculosis by this mistake. That did not happen in this country.

Mr. BEAMER. I happen to know that even today the cholera vaccine given to hogs to prevent cholera sometimes will kill many hogs.

Dr. SEBRELL. When the yellow fever vaccine was first developed, there was trouble before it was licensed. You know, yellow fever is a very serious disease. It is a virus disease. With the first yellow fever vaccine there was trouble with a disease known as hepatitis, in which another virus was accidentally in the vaccine. There were thousands of cases of hepatitis, and many died. The method of making the vaccine was immediately changed. There have been difficulties from time to time even with as old a thing as smallpox vaccine. For a while there was difficulty with children getting tetanus at the time they were vaccinated with smallpox. This was connected in many instances with wearing the shield on the arm that they used to use many years ago. This led to the abandonment of vaccination shields. There have been other incidents that have occurred.

Mr. BEAMER. Yesterday or the day before, the statement was made that in New York City, 30 percent of the young people had not availed themselves of the opportunity to get polio vaccination. I am wondering if you have any figures to indicate how many children avail themselves today of other vaccines, such as smallpox or diphtheria, or yellow fever. In other words, have you ever had 100 percent coverage or 70 percent coverage?

Dr. SEBRELL. We have no way of getting that information, Mr. Beamer. The physicians vaccinate children in their private practice, and there are also public health clinics.

Mr. BEAMER. Is it not conceivable that a 70 percent coverage is a high coverage?

Dr. SEBRELL. I would imagine so.

Mr. BEAMER. It is not the ultimate that we would like to achieve, but I wonder if the 70 percent coverage was not a high coverage in comparison with other methods of vaccination.

Dr. SEBRELL. I would think so.

Dr. SCHEELE. There is not a reporting of vaccinations as programs. That is not ordinarily reported to health departments, although there is some data on school programs. I think 70 percent is a very good record in terms of other vaccination programs, other immunization programs.

Mr. BEAMER. While it is not the ultimate you would like to achieve, still it is approaching it.

Dr. SCHEELE. Yes. We want 100 percent.

Mr. BEAMER. I have one last question I would like to ask. A statement was made that 450,000 children were tested last year. Is that correct, approximately?

Dr. SCHEELE. Yes.

Mr. BEAMER. The product of how many laboratories was used?

Dr. SEBRELL. The product of two laboratories was used in that test.

Mr. BEAMER. Is that for publication? Do you want to tell us?

Dr. SEBRELL. I think so.

Dr. SCHEELE. Parke-Davis & Co. and Lilly.

Dr. SEBRELL. This is no reflection on the others, you understand. All that was used passed all the tests.

Mr. BEAMER. I mean merely for testing purposes.

Dr. SEBRELL. Yes.

Mr. BEAMER. What was the incidence of the 450,000?

Dr. SCHEELE. I think Mr. Hinshaw had figures from which we copied. There were 56 that developed polio in the observed areas. The observed areas were the ones where the placebos had also been given; about 85 communities. That was at the rate of 25 per 100,000.

Mr. BEAMER. So much of this is so technical, I know I for one feel rather at a loss to ask questions. But I remember over the years there have been, shall we say, outbreaks or epidemics, as people referred to them, perhaps, of polio in a certain community. Is it true that occasionally a certain community would have a larger incidence of polio than maybe a neighboring city or county?

Dr. SEBRELL. That is right. And it varies from year to year. It will be bad one year and light the next year in the same area. It varies as to when it occurs. It varies in the effect on different age groups and different parts of the country. It comes at a different time in different areas of the country.

Mr. BEAMER. And that is unexplainable?

Dr. SEBRELL. Yes. We are pretty sure that the disease is transmitted by a live virus that is transmitted from person to person, getting from him to a suspectible individual. I would like to point out just one statistic that I think we should all keep in mind, that the Salk vaccine has now been given to more than 5 million children. And even including the tragic so-called Cutter incident, there are not more than around 100 or, I guess, 110 cases altogether in the more than 5 million children.

Mr. BEAMER. Is that a decrease over previous years?

Dr. SEBRELL. Well, it is too soon to tell how effective the vaccine is. I am merely pointing out how safe it is. This is a very safe product on this basis, even including this concentration of cases apparently related to one particular product.

Mr. BEAMER. Is it too soon to determine the number of cases in comparison to previous years?

Dr. SCHEELE. We have data on the number of cases to date in comparison to others. It is very difficult to make a prediction about what is going to be happening in August or September.

Mr. BEAMER. You can only compare with May 29 of other years, perhaps.

Dr. SCHEELE. We like to measure the polio season from April 1.

Mr. BEAMER. If this has been given in testimony previously, you do not have to give it.

Dr. SCHEELE. No, it has not. We measure the polio season as beginning April 1. There are cases in January, February, and March, but these are considered to be the spread cases that have come from the epidemic of the previous year. It is the sort of windup of the polio year.

Beginning April 1, and counting the 7-week period which ended May 21 of this year, there have been reported 986 cases.

Mr. BEAMER. In 1955?

Dr. SCHEELE. That is correct, sir. The median for the period 1950 through 1954, in other words, the average of a 5-year period, in that same 7-week period, is 582. So the incidence is higher this year than it has been in the median year over a 5-year period.

Mr. HARRIS. Has that been average throughout the country, or what?

Dr. SCHEELE. This gets spotty when you break it down. For example, Maine had one case this year, and it had no cases in the 5-year period. There are other instances.

Here is one in Texas. Texas has had less than the median. Texas has had 139 cases so far this year, and in the median period of the 5-year period, 189. It moves up and down. In Arkansas there are 13 cases so far in 1955 in the 7-week period, and it had 8 cases as the median previously.

Mr. HARRIS. Go across the country. How about New York?

Dr. SCHEELE. New Yorkers had twice as many cases as the median. They have had 56 cases in the 7-week period compared to 26 in the 5-year median. It is a variable sort of thing. It is difficult, always, to predict where we are going 5 weeks after that time.

Mr. BEAMER. Doctor, I have just this further thought on the bill that is presented, H. R. 6286, and the companion measure.

As I gather it, it is the intent to place the distribution and, shall we say, the final supervision within each respective State?

Mr. PERKINS. Yes, sir. You understand that there are two bills and that H. R. 6207 introduced by the chairman is not an administration proposal. The administration recommendation here is H. R. 6286, also introduced by the chairman.

Mr. BEAMER. In other words, it applies to State application for funds and the State administration of the funds?

Mr. PERKINS. That is correct.

Mr. BEAMER. And with certain regulations laid down by your agency.

Mr. PERKINS. Yes, sir. The State plans would be submitted and approved.

Mr. BEAMER. Is that not in conformity with almost any other type of fund that is administered through the States, through the Public Health Service or whatever agency they might have within the State?

Mr. PERKINS. Yes, sir. One of the basic elements underlying H. R. 6286 is that to the maximum possible extent this should be carried out with other Federal health programs on a basis that has been proven throughout the years?

Mr. BEAMER. In other words, this is not a new policy, but you are carrying it out on a basis that has been proven throughout the years?

Mr. PERKINS. Yes, sir.

Mr. BEAMER. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Williams?

Mr. WILLIAMS. Mr. Chairman, first I would like to ask a question of Dr. Scheele. I am informed that a newscaster on Monday night of this week, I believe, related the story of a 35-year-old father of a child who had been inoculated having contracted polio shortly after his child was inoculated, and dying as a result. The inference that might be drawn from that, and I believe which was intended by this commentator, was to the effect that there was a possibility that even though the child may not have contracted polio as a result of the inoculation, that nevertheless he transmitted it to his father. Doctor, have you progressed far enough in your tests to tell whether that is possible?

Dr. SCHEELE. We think it is possible. I don't know that we can ever prove it. We have to prove a relationship between some virus being excreted by the vaccinee to the virus being excreted by the second case.

Mr. WILLIAMS. Are you familiar with that particular case?

Dr. SCHEELE. I am not aware of that particular 1, but there have been some 40 cases of that type that we have entered into our record as having occurred. It is likely that they are spread from virus excretions. Whether the virus excretion in any given case has come from the vaccination or whether the individual would have been excreting virus anyway, no one could ever prove.

Mr. WILLIAMS. That has not yet been established, I presume?

Dr. SCHEELE. That is correct. We are dealing here with delicate balances within the community level between groups of individuals and the challenge by a virus, whatever the source, whether that be natural to the community or otherwise.

Mr. WILLIAMS. The second question, Doctor, is with regard to the vaccine itself. Is is necessary to keep this vaccine refrigerated when it is stored?

Dr. SCHEELE. It should be kept refrigerated, but that does not mean that it cannot be off refrigeration a part of the time during shipment. The advantage of keeping it refrigerated is that it retains its potency better than it would if kept at room temperature.

Mr. WILLIAMS. As I understand it, this vaccine is made up basically of dead polio virus, is that correct?

Dr. SCHEELE. That is correct.

Mr. WILLIAMS. That is generally the basis of the vaccine?

Dr. SCHEELE. That is correct.

Mr. WILLIAMS. As I understand it further, ever precaution is taken to see that all of this virus is dead; that the Cutter incident was suspected of being the result of live virus having gotten ino the vaccine. Is that the situation?

Dr. SCHEELE. The epidemiological evidence points in that direction, that there were quantities of live virus that had not been detected by the safety tests or crept in as contamination. The safety tests were negative on those lots of vaccine. One suspects that there may have been virus from the epidemiologic data.

Mr. WILLIAMS. In cases where there may be vaccine which had been infected with a live virus to a very minute degree, there is a possibility that a child may be given that vaccine and yet not contract polio, because his system manages to shake it off, is that right?

Dr. SCHEELE. Yes, sir. Many people have a certain level of natural immunity that they have acquired over the years.

Mr. WILLIAMS. In cases where there may be a minute quantity of live virus in the vaccine itself, which might even be insufficient to transmit polio to the child, is it possible for those live virus to "culture" or to multiply to the extent that the vaccine would become dangerous if it was improperly stored?

Dr. SCHEELE. Dr. Sebrell, I think, is more competent to answer that.

Dr. SEBRELL. It is, I believe, impossible for the virus to grow, because the growth of virus differs completely from the growth of bacteria. Bacteria will grow in solutions. The growth of a virus requires a living cell for it to grow on. That is why this vaccine has to be grown on monkey kidney cells. You cannot grow the virus unless you put living cells there. So when you filter and make the vaccine and there are no cells in it, there seems to be no possibility of having that virus multiply, such as a bacterium might do.

Mr. WILLIAMS. I realize, of course, that you have made tests along that line, or as many as you have had an opportunity to make. But the reason I have asked the questions was to make that information available to the public.

I have one more question. Perhaps this one should be directed to Mrs. Hobby.

Mrs. Hobby, in recent weeks you have been the subject of many attacks for alleged mishandling of the vaccine program, as you know. Most of those attacks originated from hostile political sources.

As a matter of fact, Mrs. Hobby, your Department has no authority under the law to establish any kind of a program at the present time, is that right?

Secretary HOBBY. That is correct.

Mr. WILLIAMS. And the program to which these attacks are directed, rather than being a program in itself, is really the matter of certifying this vaccine for use by the public, is it not?

Secretary HOBBY. That is correct, sir.

Mr. WILLIAMS. May I say, as I said a few minutes ago, the statement which has been given to the committee this morning by Dr. Sebrell should allay any fears in the minds of the public as to the action taken by the Department in withdrawing this vaccine from public use. I think you are entirely justified in the program that you have carried out thus far.

Secretary HOBBY. Thank you very much.

The CHAIRMAN. Before any other question, the Chair promised some of the press photographers that he would declare a brief recess. It shall be very brief.

The committee will now stand in recess for a few minutes.

(Brief recess.)

The CHAIRMAN. The committee will be in order.

Mr. Staggers, do you have a question?

Mr. STAGGERS. Not at this time, no.

The CHAIRMAN. At this point, I want to ask Dr. Scheele one question. This information that has been discussed this morning is the result of one of our staff members making a study of the Francis report. My question is, Dr. Scheele, has the Public Health Service or your staff made any evaluation of the data used by Dr. Francis in his report?

Dr. SCHEELE. Yes, sir. Several members of our staff have evaluated that data; yes, sir.

The CHAIRMAN. The staff study made has raised some questions, some of which have been raised already by Mr. Hinshaw. I have here a brief memorandum prepared by the staff. I will not take the time now to ask questions about these, but I should like, Doctor, to submit this memorandum and this set of tables to the Public Health Service and ask that you have someone on your staff go over this table and perhaps be able to present to the committee some answers to some of the questions that arise from this tabulation which is taken from Dr. Francis' report.

Dr. SCHEELE. Yes, sir, Mr. Chairman. We will be very happy to do that.

(The memorandum and comments follow:)

MAY 26, 1955.

Memorandum to: Mr. Priest.
From: Andrew Stevenson.
Subject: Evaluation of the 1954 Tests of the Salk Vaccine.

Within recent days I have secured a copy of the Francis Evaluation of the 1954 Field Trials of Poliomyelitis Vaccine, and have attempted some statistical analysis of it.

There appear to be several areas wherein the 1954 data show results that would seem to require further explanation than that given in the Francis report. Perhaps study and explanations of these matters might throw some light on the problems which have arisen this year in the mass inoculations.

THE 1954 TESTS, METHODS USED

Two tests were run. The first, called the placebo, was run in 64 counties in 11 States, and involved 749,000 children in the 1, 2, and 3 grades. In this test, 200,000 children were vaccinated, and 200,000 children were inoculated with placebo, with 330,000 children not inoculated.

The other test was run in 33 States, and consisted of vaccinating 2d grade children, and observing 1st and 3d grade children as controls. Of the 1,080,000 children involved, 222,000 2d graders were vaccinated and 123,000 2d graders not inoculated, with 725,000 1st and 3d graders being observed. This is designated as the "observed areas" test.

On the basis of the attack ratio, i. e., the incidence of polio among those vaccinated compared with the incidence among those not vaccinated, the conclusion is reached that there was substantially less polio—at least of the paralytic type—among those vaccinated than among those who were not.

RESULTS OF BOTH TESTS, 6-YEAR-OLDS

On page 39 of the report, it is stated: "Since the difference in attack rate between vaccinated and control 6-year-olds is not statistically significant, a

question which might be raised as to how and why this group differed from the older children." It would appear appropriate to inquire into whether any further explanation of this has been developed, especially since consideration has been given to mass inoculation of the 6–9 year group ahead of all others.

PLACEBO TEST—DIFFERENCE BETWEEN PLACEBO INOCULATED AND NONINOCULATED CONTROLS

Table 2b, page 25, and table 3a, page 26, show the results of vaccination of 200,000 children, inoculation of 200,000 children with placebo, and observation of 330,000 more children in the same 1, 2, and 3 grades. It will be observed that the attack rate of paralytic polio, per 100,000 children, was 16 for vaccinated. 57 for placebo inoculated, and 36 for the noninoculated children.

While comparisons are made in the report of the efficacy of vaccination as between the vaccinated and the placebo inoculated, I do not find any discussion of the fact that those who were placebo inoculated had an attack rate of 57 compared with those to whom nothing was done of an attack rate of 36.

I have analyzed the underlying data, as shown in the appendix, for this placebo-control group to determine whether the United States average of 57–37 is reflective of all areas, or shows the influence of any one State. It will be noted from table I attached, that in four far-western States the ratio was 93 to 54, that in Illinois, Iowa, and Ohio the ratio was 99 to 20, in Michigan, 49 to 38, and in New York, 43 to 30. Only in Massachusetts was the ratio reverse, being 77 to 91.

Expressed in another way, the attack ratio for 330,000 noninoculated children was 36. The attack ratio for 400,000 either placebo or vaccine inoculated children was 36. Inasmuch as half of the latter were vaccinated, with half being placebo inoculated, it would be expected that the inoculated group would have a lower attack ratio since half the group was vaccinated.

It would seem significant to have the reasons developed why children who were inoculated with the control fluid should have incurred more paralytic polio than those who were not touched.

PLACEBO TEST ON A COUNTY BASIS

To check these data on a regional or national basis, which are influenced by the weighting of the numbers of children involved, I have made a frequency distribution on a county basis, assuming that there is some homogeneity within each county of the type of children, etc.

Of the 64 counties involved in the test, the distribution is as follows:

	Counties
Vaccinated—Placebo—Noninoculated	12
Vaccinated—*Placebo*—Noninoculated	11
Vaccinated—Placebo—*Noninoculated*	6
Vaccinated—*Placebo*—*Noninoculated*	16
Vaccinated—Placebo—Noninoculated	3
Vaccinated—*Placebo*—Noninoculated	1
Vaccinated—Placebo—*Noninoculated*	2
Vaccinated—*Placebo*—*Noninoculated*	13
Total	64

NOTE.—Italic represents presence of paralytic cases.

Hence it will be seen that of the 64 counties, there were 16 in which no paralytic cases developed in the placebo inoculated or the noninoculated. There were 12 counties where paralytic polio developed in the placebo inoculated but not in the noninoculated, and 8 counties where it developed in the noninoculated and not in the placebo inoculated. Analysis of the attack ratio in the 29 counties where it developed in both groups, shows 20 where the ratio is higher for the placebo than for the noninoculated, 2 where it is the same, and 7 where it is less. In summary, 32 counties show placebo inoculation led to a higher paralytic attack ratio, while 15 showed less, than occurred among those who were not inoculated.

Parenthetically, a comparison of the county rates of paralytic polio among those vaccinated, and those not vaccinated, shows 12 where no polio occurred

in any group. Of the remainder polio occurred in 3 counties among the vaccinated only. Adding 6 counties where the attack ratio was higher for the vaccinated than for the nonvaccinated, the result is 9 counties where the rate among the vaccinated was higher than the nonvaccinated, compared with 43 where it was less. This may be compared with the numerical average of 16–44.

OBSERVED AREA TEST—DIFFERENCE BETWEEN 1–3 GRADERS AND 2D GRADERS, NOT VACCINATED

I also have made a cursory examination of the data underlying table 2b., page 25, and table 3b., page 27, bearing on the attack ratios among the 1,080,000 children where 222,000 2d graders were vaccinated and 123,000 were not, and where the 725,000 children in the 1st and 3d grades were used as controls.

While it is evident that the attack ratio of paralytic polio for the vaccinated 2d graders was substantially below the 1st and 3d graders who were not vaccinated, being 17–46 per 100,000 children, it is also evident that the noninoculated 2d graders had a lower incidence than the 1st and 3d graders, being 35 as against 46.

A breakdown of this test on a State basis is shown in the attached table II. Greater discrepancies are shown on a State or regional basis than nationally. In New England the 1st and 3d graders were more prone to paralytic polio than the noninoculated 2d graders by 63 to 30. In the 6 South Atlantic Seaboard States this ratio was 33–17, while in the Western States this difference disappears.

Whether there is an explanation for this, I do not know, nor for that matter what the influence in the 1st and 3d grade controls may be of the presence of 6-year olds, about whom earlier the report has raised a question.

OBSERVED AREA TEST—VACCINATION IN THE SOUTHWEST STATES

Parenthetically it is interesting also to note that in the test where the 2d grade only was vaccinated, the Southwest presents a decidedly different pattern from the rest of the country. In the States of Oklahoma, Arkansas, Louisiana, and Mississippi, involving 115,000 children, the paralytic attack ratios for the vaccinated were 33, for the 1st and 3d grade not vaccinated 24, and for the 2d grade not vaccinated 19. With the addition of the State of Texas, with some 213,000 children involved, making a total of 330,000 for the 5 States, the attack ratio among the 55,000 vaccinated 2d graders was 27, among the 222,000 1st and 3d graders not vaccinated was 32, and among the 47,000 not vaccinated 2d graders was 26.

What the explanation may be for this phenomenon is not set out in the report. It would seem appropriate to make further inquiry as to the dates when the tests were made, the nature of the children, economic conditions, or other factors which might render some explanation.

GAMMA GLOBULIN

In passing it is noted 1 percent of the placebo test children had been given gamma globulin. It would be of interest to know if any of them incurred polio, though the number is so small, any definite conclusion could not be drawn.

TABLE I.—*Distribution of study cases by diagnostic classification, vaccination studies, and by field trial areas—placebo areas*

	Study population				Paralytic cases (number)			
	Total	Vaccinated	Placebo	Not inoculated	Total	Vaccinated	Placebo	Not inoculated
Alabama	10,670	4,136	4,088	2,363				
California	15,049	3,633	3,539	8,016	7		1	6
Washington	19,935	5,531	5,510	8,646	5	2	1	2
Montana	4,502	1,586	1,544	1,329	1		1	
Utah	42,766	11,822	11,815	17,447	31	2	18	11
4 Western States	82,252	22,592	22,408	35,438	44	4	21	19
Illinois	24,637	6,762	6,757	10,780	12		9	3
Iowa	19,033	6,187	6,209	6,214	5	1	3	1
Ohio	34,039	7,921	8,070	17,789	13	1	9	3
3 Midwestern States	77,979	20,870	21,036	34,783	30	2	21	7
Michigan	119,771	26,026	26,147	65,596	42	3	13	26
4 Midwestern States	197,750	46,896	47,183	100,379	72	5	34	33
Massachusetts	46,280	14,173	14,137	17,565	32	5	11	16
Total, except New York	336,923	87,687	87,816	155,745	148	14	66	68
New York:								
Erie	55,272	10,473	13,788	25,589	6		3	3
Monroe	29,843	10,578	10,528	8,063	2		2	
Nassau	70,120	21,599	21,581	25,904	21	4	10	7
Onondaga	21,157	6,708	6,751	7,347	16	4	3	8
Suffolk	23,382	5,877	5,983	11,107	5	1	3	1
Westchester	37,491	11,065	11,007	14,822	21	3	7	11
New York City	85,345	19,183	19,434	42,468	24	4	11	14
14 counties	89,313	24,483	24,361	39,158	22	3	10	9
Total, New York	411,923	112,968	113,413	174,456	122	19	49	53
Total, 11 States	749,236	200,745	201,229	330,201	270	33	115	121

	Paralytic cases per 100,000				Nonparalytic cases							
					Number				Per 100,000			
	Total	Vaccinated	Placebo	Not inoculated	Total	Vaccinated	Placebo	Not inoculated	Total	Vaccinated	Placebo	Not inoculated
Alabama												
California	46		28	75	1		1					
Washington	25	36	18	23	1	1						
Montana	22		64									
Utah	72	17	152	63								
4 Western States	54	18	93	54	2	1	1		2	4	4	
Illinois	49		133	27	6	1	4	1	24	15	59	9
Iowa	26	16	48	16	1			1	5			16
Ohio	37	12	111	16	7	2	3	2	20	25	37	11
3 Midwestern States	38	9	99	20	14	3	7	4	18	14	33	11
Michigan	35	11	49	38	11	1	2	8	9	4	8	12
4 Midwestern States	36	10	72	32	25	4	9	12	13	8	19	12
Massachusetts	69	35	77	91	6	2	2	2	13	14	14	11
Total, except New York	44	16	75	43	33	9	12	14	10	8	14	9
New York:												
Erie	11		32	12	3	1		2	5	7		8
Monroe	7		19		5	2	2	1	17	19	19	12
Nassau	30	19	46	27	11	4	5	2	16	19	23	8
Onondaga	76	60	44	108	17	6	4	7	80	89	59	95
Suffolk	21	17	50	9	1			1	4			9
Westchester	56	27	64	74	1			1	3			7
New York City	34	21	57	33	8	2	3	3	9	10	15	7
14 counties	25	12	41	23	9	2	1	5	10	8	4	13
Total, New York	30	17	43	30	15	17	15	22	13	15	13	12
Total, 11 States	36	16	57	36	88	24	27	36	12	12	13	11

TABLE II

	Study population				Paralytic cases			
					Number			
	Total	2d grade, vaccinated	1st and 3d grades, not vaccinated	2d grade, not vaccinated	Total	2d grade, vaccinated	1st and 3d grades, not vaccinated	2d grade, not vaccinated
Total population	1,080,680	221,998	725,173	123,605	415	38	330	43
Maine	9,170	1,706	6,603	1,146	5		5	
New Hampshire	4,915	1,089	3,341	474	7	1	6	
Vermont	4,238	858	2,860	514	4		3	1
Rhode Island	13,374	3,444	8,716	1,157	10	3	6	
Connecticut	73,066	17,887	48,315	6,632	26		24	2
New England	105,063	24,984	698,35	9,923	52	4	44	3
New Jersey	70,729	15,335	46,750	8,276	27	3	21	3
Pennsylvania	16,812	4,494	11,157	1,131	5	1	3	1
Delaware	15,204	2,416	10,196	2,485	7		7	
Virginia	50,523	10,601	34,411	5,311	11	1	9	1
West Virginia	35,922	6,653	23,960	5,029	5		5	
North Carolina	13,568	2,642	9,329	1,411	1		1	
South Carolina	14,729	3,127	9,967	1,080	4		3	1
Florida	17,219	3,102	11,534	2,172	10	1	8	1
South Atlantic	147,165	28,541	99,397	17,688	38	2	33	3
Indiana	63,725	15,336	42,809	5,222	35	2	31	2
Wisconsin	44,141	10,414	29,751	3,770	8		8	
Kentucky	38,544	7,380	25,086	5,880	39		34	5
Tennessee	43,612	9,648	29,382	4,377	18		14	4
Arkansas	31,995	5,124	21,400	5,272	6	1	4	1
Oklahoma	41,110	8,857	27,588	4,194	14	2	10	
Louisiana	23,712	3,612	15,768	4,170	4	1	2	1
Mississippi	18,450	3,427	12,802	2,047	7	3	3	1
Texas	213,049	34,005	144,013	31,032	71	8	53	9
Southwest central	328,316	55,025	221,571	46,715	102	15	72	12

North Dakota	6,338	1,604	4,164	509	6	1	5	
South Dakota	4,398	1,133	2,905	344	1		1	
Nebraska	22,045	5,542	14,903	1,502	8	1	6	1
Kansas	33,407	7,581	22,231	3,170	9	2	5	2
Missouri	45,853	9,220	30,741	5,600	26	4	19	3
North West Central	112,061	25,080	74,944	11,125	50	8	36	6
Wyoming	6,509	1,289	4,482	667	6		5	1
Colorado	55,220	13,684	36,759	4,429	23	3	18	2
New Mexico	13,613	2,999	9,144	1,206	4		4	
Idaho	11,453	2,735	7,885	767	3		3	
Nevada	3,135	782	2,170	161	2		2	
Oregon	20,602	4,432	13,951	2,268	3		2	1
North Pacific	110,532	25,921	14,391	9,498	41	3	34	4

TABLE II—Continued

	Paralytic cases—continued				Nonparalytic cases							
	Per 100,000				Number				Per 100,000			
	Total	2d grade, vaccinated	1st and 3d grades, not vaccinated	2d grade, not vaccinated	Total	2d grade, vaccinated	1st and 3d grades, not vaccinated	2d grade, not vaccinated	Total	2d grade, vaccinated	1st and 3d grades, not vaccinated	2d grade, not vaccinated
Total population	40	17	46	35	90	18	61	11	8	8	8	9
Maine	53		75									
New Hampshire	142	92	180									
Vermont	94		105	195	1			1				
Rhode Island	75	87	69									
Connecticut	36		50	30	12	3	9		16	17	19	
New England	49	16	63	30	13	3	9	1	12	12	13	10
New Jersey	38	20	45	36	6	1	4	1	8	7	9	12
Pennsylvania	30	22	27	88								
Delaware	46		69									
Virginia	22	9	26	19	8	2	6		16	19	17	
West Virginia	14		21									
North Carolina	7		11									
South Carolina	27		30	78								
Florida	58	32	69	46								
South Atlantic	26	7	33	17	8	2	6		5	7	6	
Indiana	54	13	72	38	4	3	1		6	20	2	
Wisconsin	18		27		2	1	1					
Kentucky	101		136	85	5	1	3	1	13	14	12	17
Tennessee	41		47	91	3		2	1				
Arkansas	19	20	19	19								
Oklahoma	34	26	36		7		7		17		25	
Louisiana	17	27	13	24								
Mississippi	38	88	23	49	2		2					
Texas	33	23	37	20	19	3	12	4	9	9	8	13
Southwest central	31	27	32	26	28	3	21	4	9	5	9	9

North Dakota	95	62	120	----	1	----	----	1	----	----	----	----
South Dakota	23	----	34	----	----	----	----	----	----	----	----	----
Nebraska	36	18	40	66	----	----	----	----	----	----	----	----
Kansas	27	26	22	63	5	2	3	----	15	26	13	----
Missouri	57	43	62	54	10	1	7	2	22	11	23	36
North West Central	45	32	48	54	16	3	10	3	14	12	13	27
Wyoming	92	----	112	149	3	----	3	----	----	----	----	----
Colorado	42	22	49	45	1	----	1	----	----	----	----	----
New Mexico	29	----	44	----	1	1	----	----	----	----	----	----
Idaho	26	----	38	----	----	----	----	----	----	----	----	----
Nevada	64	----	92	----	----	----	----	----	----	----	----	----
Oregon	15	----	14	44	----	----	----	----	----	----	----	----
North Pacific	37	12	46	42	5	1	4	----	5	4	5	----

COMMENTARY OF DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

The following statement is a point-by-point commentary on the analysis of the Francis Report on Poliomyelitis Vaccine prepared by Mr. Andrew Stevenson.

Mr. Stevenson under the caption "Results of Both Tests—6-year-olds," first questions the priority for mass inoculation of 6-to-9-year-old children in view of the statement made in the Francis report that there was no statistically significant protection evident in 6-year-olds. In considering this question, it should be noted that the placebo-controlled test was the only scientifically sound test and that it showed substantial protection in the vaccinated group of first, second, and third graders—the 6-to-9-year-olds. It is true that the 9, 8, 7 and 6-year-olds had progressively decreasing protection in that order. In view of the fact, however, that the 6-year-olds did enjoy some protection, it is evident there was no reason to exclude them from the 7, 8, and 9-year-olds, the entire group of which showed evidence for priority for inoculation.

Mr. Stevenson also inquires as to reasons which might explain these differences in protection. The Francis report does not clarify this fact since the report indicates that 6 and 7-year-olds had much the same serological response to vaccine and were examined under same diagnostic criteria. It is true, however, that the older the age group, the more past natural experience they would have encountered with one or more types of poliomyelitis virus. Natural immunity, therefore, may account for some of the increased protection with increasing age.

Under the caption "Placebo Test—Difference Between Placebo Inoculated and Noninoculated Controls," Mr. Stevenson points out the attack rate among the total of 330,000 noninoculated children was 36 per 100,000 as contrasted to an attack rate of 36 per 400,000 among the total inoculated group (vaccinated and placebo). The attack rate among the inoculated group, he feels should have been lower in view of the fact that half of this group received the vaccine, not the placebo.

The difficulty here almost certainly lies in comparing the inoculated and noninoculated children on an equal basis. Several factors would indicate that this comparison should be made cautiously.

(1) Children who were inoculated (either with vaccine or placebo were almost certainly observed more intensely and completely for the occurrence of poliomyelitis, and any untoward occurrences, especially of nonparalytic polio or symptoms resembling it, were reported more often.

(2) As indicated by the Francis report, proportionately more of children in higher income groups were vaccinated than those in lower income groups. It is generally known that groups of higher social, economic, cultural, and educational levels have a higher incidence of poliomyelitis, and these groups, moreover, also report illness more frequently than groups of lower economic or social levels.

(3) Those children who had had poliomyelitis at any time during the years prior to the time of vaccination and, who were therefore likely to be immune, were likely to be in the noninoculated group.

Mr. Stevenson also points out that the differences between the placebo-injected group and the noninoculated group were reversed in one geographic area. There is some question as to whether the differences by geographic area are really significant due to the small number of cases involved. In all, the similarity between areas would appear somewhat striking in view of the different proportions of the three above-mentioned factors which may have occurred in different geographic areas.

Under the caption "Placebo Test on County Basis" Mr. Stevenson's questions again are based on comparisons between placebo-injected and noninoculated children. If we can now assume the principle that these groups cannot be compared on an equal basis, the results appear compatible with the general conclusions of the Francis report. This same principle operates, we feel, in Mr. Stevenson's analysis under the caption "Observed Area Test: Difference Between First to Third Graders and Second Graders Not Vaccinated." It may be noted that the same differences result in placebo areas as in observed areas. (Placebo areas: Vacinnated rates 16, not inoculated 36; observed areas: vaccinated 17, Second grade not inoculated 35).

In his last major point, under "Observed Area Test—Vaccinated in Southwestern States," Mr. Stevenson points to lack of evidence of protection in five selected States of the Southwest. There was no placebo test carried out in these States, and hence it is difficult to make a valid comparison. As indicated in the Francis report itself, the observed test groups are not as scientifically sound as the placebo test and considerable variations in observed trial results can be expected.

In view of the natural variation in the occurrence of the disease, the different potencies of the vaccines used and the nature of the studies carried out, it is not surprising that local variations in data, as pointed to by Mr. Stevenson, should have occurred. In our opinion, however, they do not contradict the general conclusion of the Francis report that the vaccine gave substantial protection against paralytic poliomyelitis to first-, second-, and third-grade children.

The CHAIRMAN. There is one other question before I go ahead. Mr. Harris had to leave, and he asked me two questions to which I did not have the answer. I ask them now because he was very anxious to get them answered.

I think maybe, Dr. Scheele, you discussed somewhat the other day the question of the minimum and the maximum lapse of time between the first and the second shot. What is considered to be the minimum and the maximum for effectiveness?

Dr. SCHEELE. The work of Dr. Salk on that subject indicates that the second injection should not be given earlier than the third or fourth week. That is, the second injection does not give quite as much additional antibody response in the vaccinated child if it is given earlier than that. However, his data also show that it may be given 5 weeks, 6 weeks, 8 weeks, or 12 weeks later with very excellent effect. As a matter of fact, there are enough variations between different human beings and the way they react in producing antibodies that no one could really establish any exact formula for time scales here that would be universally applicable.

The CHAIRMAN. And then there is one further question. Does the body temperature, say, of a child, at the time of the inoculation have any effect on the effectiveness of the inoculation one way or another, or on the vaccination, maybe I should say.

Dr. SCHEELE. I do not think we have any scientific data on that. I doubt that it would have much effect, if any. There is one very important medical point. If a child has a fever, he probably should not be vaccinated.

The CHAIRMAN. I think it was a question that had been brought to Mr. Harris personally, and he was seeking an answer to that question.

Dr. SCHEELE. The reason for not vaccinating, one reason, is if the child has fever maybe it is coming down from polio, and one should wait until that fever ends and then go ahead with the vaccination.

The CHAIRMAN. Thank you, Doctor.

Mr. Rogers, do you have a question?

Mr. ROGERS. Thank you, Mr. Chairman. Mrs. Hobby, first I want to state my concern about your husband's health and state that I hope he has a speedy recovery.

Secretary HOBBY. Thank you.

Mr. ROGERS. I have 1 or 2 questions which are perhaps a great deal different. The first question is in connection with what the chairman has been discussing.

Dr. Scheele, if the child has received the first vaccination, and the parents are disturbed by what has transpired here in the past several weeks, what assurance can be given them that most of the danger of the child getting any polio from a shot, if polio was caused by the vaccination, is lessened insofar as the second shot is concerned?

Dr. SCHEELE. Well, in the first instance, the children who have been vaccinated have now pretty well run out the incubation period, the maximum incubation period, that we know about in polio. So they are not going to get polio from the first injection now. The other thing is that of those who had these injections, the majority will have

developed some anibodies that they did not have before. In other words, they will have more protection within their bodies than they would have had if they had not been vaccinated. While they will not have the maximum protection that we would like to have them have after the second and third injection, they will have had enough, most of them, after one injection, to be able to take a pretty heavy assault of polio virus without coming down with paralytic polio. In other words, they will have had successful vaccinations.

Mr. ROGERS. In other words, there is no reason why a child who has had the first vaccination should fear the second.

Dr. SCHEELE. No, sir.

Mr. HINSHAW. I think you should repeat that, because that is a very important question.

Mr. ROGERS. I want that shown. I have one child who had a fever after the first shot, and you can imagine my concern. But many of the parents are hesitating as to whether or not their children should submit to the second shot. I would like to see the American people assured that that first shot has provided the child with certain antibodies that would measurably lessen any possibility of polio from the second shot even if you could ever determine that the shot is what caused the polio in the first instance.

Dr. SCHEELE. As a matter of fact, the children who have had the first injection would be able to take a greater assault of virus no matter what the source might be, and they should have the second injection because they will have just that much more protection in their blood streams if they come in contact with polio.

Mr. ROGERS. Let me ask this, too. If they have not developed any serious reaction insofar as the polio area is concerned from the first shot, that would be a very clear indication that the shot was not going to affect them, whether it was the first, second, or third?

Dr. SCHEELE. That is correct, sir; yes, sir. Incidentally, on fevers, I might say one additional thing. Of course, everyone is on edge, and every time one child is a little off his eating or something else, or has a fever, if he has been vaccinated, one thinks of the vaccination. But there is no reaction to the vaccination itself. It does not cause fever. There are a lot of other viruses floating around the community at the moment. Right here in the District of Columbia, there are APC viruses that are hitting children pretty hard, the pediatricians tell us, at the present time. We need some vaccines for that, too, and are working pretty hard for that.

Mr. ROGERS. Does the reaction from the polio vaccine create a fever?

Dr. SCHEELE. No, sir, it does not. There is no effect, except possibly a little sting in the arm from some of the material that may leak a little bit along the track.

Mr. ROGERS. Had I known that earlier, I probably would have been a little more frightened when my child had a fever from some other virus. Let me ask a question in regard to the licenses. As I understand it, there are six laboratories that are licensed to produce this vaccine. What mechanism was used to determine who would be licensed and who would not be licensed.

Mr. SCHEELE. With your permission, we would like to ask Dr. Sebrell to answer that.

Dr. SEBRELL. The laboratories all filed an application for a license, and in this case, these applications were filed before the Francis report, from all of the manufacturers.

Mr. ROGERS. How many would that be?

Dr. SEBRELL. That would be six.

Mr. ROGERS. I mean all of the manufacturers.

Dr. SEBRELL. That is all of them. That is all that are making it or who appear to wish to make it. There are no more factories in the United States. So these were on hand and had filed them, and they had been accepted and their plants inspected. They had been working with Dr. Salk for a long time previously. They had made vaccine for the field trial. They were told that licenses would not be granted to anyone until the results of the field trial were made known by Dr. Francis, because it was on this field trial that the determination was made that the product had any potency in immunizing against polio. Of course, at the same time, it provided additional evidence of the safety of the product in four hundred thousand-odd children. But the reason for holding up until the Salk report came out was that this was the demonstration that it was effective in preventing polio and, we would not license them unless the product was shown to be effective. They were all granted on the same day. The recommendations from Dr. Workman in Ann Arbor were telephoned in. They were immediately transmitted to Dr. Scheele. He immediately transmitted them to the Secretary, and all the licenses were issued simultaneously.

Mr. ROGERS. Doctor, do I understand this: There were no applications for license denied?

Dr. SEBRELL. That is correct.

Mr. ROGERS. I thought I understood you to say that these six manufacturers are the only ones in the United States who are capable of producing?

Dr. SEBRELL. No, I did not say they are the only ones who are capable. I said the only ones who are capable and who have indicated that they want to.

Mr. ROGERS. That is the point. There are other laboratories who could produce this vaccine if they decided to go into that field.

Dr. SEBRELL. Yes.

Mr. ROGERS. And there is no reason why they could not receive a license if they wanted to make application and meet the requirements?

Dr. SEBRELL. That is correct. Anyone can file an application.

Mr. ROGERS. I have one other thing and then I will quit. Do you feel it would be easier to police the situation from a safety standpoint if the number of manufacturers were kept small?

Dr. SCHEELE. Yes, it is easier. I mean it is in proportion to the number of manufacturers, actually. But these are very competent people. These manufacturers make dozens of other biological products. The policing, as you refer to it, is not too complex.

Mr. ROGERS. Doctor, approximately what investment was required to get into this polio-vaccine manufacture?

Dr. SCHEELE. We do not know that. The manufacturers would have to answer that.

The CHAIRMAN. May the Chair state that before all of these hearings are concluded, we expect, if possible, to have some representative of one of the manufacturing laboratories before the committee, and no doubt that information can be obtained at that time.

Mr. ROGERS. Thank you, sir.

The CHAIRMAN. Mr. O'Hara?

Mr. O'HARA. I note that the bill provides and I do believe I understand why, the priority for the use of this vaccine as to children. Why is that, Doctor?

Dr. SCHEELE. The children are the most susceptible. There are some variations from one part of the country to the other, but generally speaking the age period of 5 to 9 contains the children that are most susceptible as compared to the 1 through 4-year group, and the 10 through 14, and then 14 through 19.

Mr. O'HARA. What is considered the next most susceptible group?

Dr. SCHEELE. Then we go into pregnant women. We do not have too good data beyond that except to say that about 20 to 22 percent of the cases occur in people over 20, between 20 and 45.

Mr. O'HARA. I wonder, with only a layman's knowledge of the susceptibility of pregnant women, why some consideration was not given to that factor, Doctor?

Dr. SCHEELE. This is a priority matter. Their susceptibility is less than that of children. There are other complications in the problem of giving it to them. They are not as readily accessible, in a sense, for the giving of it.

Mr. O'HARA. Would it not be true that they should be given the next priority, if there is such a thing? I do not want to complicate this problem, Doctor.

Dr. SCHEELE. Generally speaking, I think we would say that the next priority after the 5 to 9 would be the 1 through 4. Next after that are children 10 to 15. This is all based on risk as it has shown up in past experience.

Mr. O'HARA. I had understood that the polio affected pregnant women.

Dr. SCHEELE. Our problem here is if we should have enough vaccine they could all have it. They should all have it.

Mr. O'HARA. I realize that as a practical situation. I suppose it becomes a matter of practical administration within the States rather than attempting to create any other priorities.

Now may I ask you are there any known bad effects of this vaccine such as is there any liability of impotency or any of the things which are sometimes called byproducts of these vaccines.

Dr. SCHEELE. All of the testing which has been done by Dr. Salk and by others, by the field trial, and the results which have emerged in the short period that has elapsed since the 5 million children have had it, does not show that there are any side effects.

Mr. O'HARA. It is not like some of our drugs which have been created which have left some bad byproducts in results?

Dr. SCHEELE. That is right. It is not very likely that a material of this sort would be apt to leave bad side effects of that type.

Mr. O'HARA. From the experience that you have had, while I realize you cannot prophecy indefinitely, there is none anticipated; is that correct?

Dr. SCHEELE. That is correct, sir. We have some parallel experiences. Yellow-fever vaccine has been used, especially on American military personnel who were going into tropical areas, and it has been used on many other nonmilitary personnel going into those areas. Possibly some members of this committee have had it before going off on some of your inspection trips. We do not have any side effects of that sort in these cases. This is a parallel or somewhat parallel-type vaccine. So one would extrapolate from that that it would be unlikely to have anything of that sort.

Mr. HINSHAW. Will my friend yield?

Mr. O'HARA. Yes.

Mr. HINSHAW. After taking yellow-fever vaccine, which I have done on occasion, I have always had a slight reaction to it.

Dr. SCHEELE. Yes.

Mr. HINSHAW. That is one of the things that you get a reaction from.

Dr. SCHEELE. That is true. There is a reaction. Well, even typhoid fever, often.

Mr. HINSHAW. Yes, and I get it from that, too.

Dr. SCHEELE. It is most interesting that this polio vaccine is quite parallel with typhus vaccine. In typhus vaccine all you get is some needle sting. There is formalin in the material, in the typhus vaccine, so as they pull the needle out, there is some deposited in the track, and you get a momentary sting and then it is gone. With yellow-fever vaccine, I guess everybody who had it has about the reaction that you had.

Mr. HINSHAW. I had a 3-day yellow-fever case.

Mr. O'HARA. May I address one more question to the Secretary. I am not quarreling about any program which gets this vaccine to all children of this country. Is there going to be any priority which is going to limit it first to use in this country before it is shipped overseas?

Secretary HOBBY. Mr. O'Hara, that is in the report which was made to the President. I believe it was recommendation either 10 or 11. I think perhaps this will answer your question more specifically. Recommendation No. 11 was on international supply. This was the report to the President: "That you designate a special committee to further study methods for assisting other nations of the world."

Mr. O'HARA. Let me just be practical. Are we going to consider all the world or are we going to start in considering this country first in this program? I mean in the light of the limited manufacture of it at the present time.

Secretary HOBBY. There has been, and I believe I am speaking correctly, Mr. O'Hara, and if not, Dr. Scheele can correct me, no quota for export established.

Mr. O'HARA. There has been no quota for export established?

Secretary HOBBY. No, sir. If you will remember, Dr. Salk and several other of the laboratories, volunteered to allow scientists from other countries to come into their laboratory and study the techniques. As you recall, the Secretary of State did make available to the American embassies everywhere all pertinent information on this formula so that other countries would have the information and, if they liked, might send their scientists to this country. I think it would be reassuring to you, Mr. O'Hara, and to the committee—there are other countries presently making this vaccine. As Dr. Scheele and Dr. Sebrell will tell you, Canada is making it, and I believe Germany is making some, and also Sweden, and Denmark.

Has England put hers into production?

Dr. SCHEELE. Not yet, but they are developing their plant.

Mr. O'HARA. My viewpoint was not intended provincial or selfish, but I realize under the present conditions there is a limited manufacture. There will be all kinds of attempts, to get it all over the world. I have no reason to doubt that. But I do think in the control of it, we should certainly give at least first priority to the children of

the United States for this which has been developed in the United States, and then extend our scientific benefits to all the rest of the world.

Secretary HOBBY. Well, as I said, we have made it available because it is a complicated vaccine. The laboratories have invited scientists of other countries in the world to come here. I am sure that the committee appointed by the President will bear all of these things in mind.

Mr. O'HARA. I have one other question, Madam Secretary. With reference to this proposed $28 million, where has there been any requirement that this money be used? I mean, why is it not possible if we are going to follow out the theory of distribution to the States, that they are perfectly capable of taking care of any of the costs of immunization or vaccination of the children whose parents cannot pay? Why should there be any distribution of funds for this vaccination from Federal funds?

Secretary HOBBY. Mr. O'Hara, I will answer part of it first, and I will ask Dr. Scheele to check me on the rest. As you know, there are not many legislatures in session at the present time. I am sure you also know that few health departments would have funds on hand to do this, or few governors would have emergency funds on hand to do this. We did try to develop, and I am sure you are familiar with the formula, a formula that would take care of all the children whose parents could not pay. I believe that the formula here is broad enough to accomplish that. I believe I am correct in saying this.

May I go back a minute to give you a little background on how we arrived at where to put this in the health budget and the sum. In talking with, I think, 46 governors rather than 48 governors who were here for their conference, they were kind enough to give the Department four and a half hours one afternoon to be brought up to date on all the programs, and this took, I am sure, about an hour. Then the governors adopted a motion to appoint an advisory committee of governors to work with the Secretary on this matter. They, themselves, pointed out that their legislatures were not in session, that their State departments of health did not have the funds, and that in many, many cases the governors did not have sufficient funds in the emergency fund to take care of this.

Mr. O'HARA. In that connection, are these funds only for vaccine, or the vaccine plus the doctor's service?

Secretary HOBBY. No, sir. This is for money for the vaccine or, in lieu of money, the vaccine itself. The State departments of health work differently in the ways they handle either money or materials they receive from the Federal Government now. So we put it so that they could proceed here as they do in respect to their other programs.

Mr. O'HARA. Then is your answer that it is only for the vaccine?

Secretary HOBBY. I am sorry. It is only for the vaccine.

Mr. O'HARA. How is the child going to get vaccinated if the doctor also wants to be paid?

Secretary HOBBY. Well, Mr. O'Hara, in the States now, and I am not sure that I am speaking for all 48 of them, the State health department and the local health departments of the city and county now have public health clinics in which children are given different immunizations, diphtheria antitoxin—what are some of the others?

Dr. SCHEELE. Smallpox.

Secretary HOBBY. That program goes on now. So given the vaccine, that can be included in the present program.

Mr. O'HARA. That may be true in some localities, but those services may not be available in others. I am quite familiar with my own district, for example, and if you were to ask me if they are all covered, I would not be sure, by those types of services. I think you will find in this country a situation very much in existence where the vaccination will be given by the local doctors and probably should be.

Secretary HOBBY. May I ask Dr. Scheele to comment on how the State and Territorial health officers work that out?

The CHAIRMAN. If the gentleman will yield, I will state that we have already written a letter to the president of the State and Territorial health associations asking him to testify on this bill for the States.

Mr. O'HARA. These were practical things that came to my mind.

Mr. MACDONALD. Would the gentleman yield?

Mr. O'HARA. Yes.

Mr. MACDONALD. Doctor, would you explain, at the same time as you are explaining that to Congressman O'Hara, why it would be necessary to set up this separate agency when you do have this Children's Bureau working and functioning very efficiently?

Dr. SCHEELE. Well, really there are two questions. I will try to answer the second one first, if I can.

It has been traditional for American physicians to give their services free to needy people. In some States, in some communities, some localities, there could be organized programs in which this vaccine would be used, that is, a portion of the vaccine used would be from this source and would be for the needy children. In other instances they would follow the pattern that is followed in many health departments. Physicians can obtain vaccine for patients who are needy from the health department to place in their own refrigerators and it can then be given in their own individual offices. So by one or the other of those two devices it would be feasible to accomplish this if the mothers and fathers would present their children.

In answer to your question, Mr. Macdonald, this does not set up a new agency. This is a special program related to a particular categorical thing, polio vaccine. The authority is vested in the Secretary. She would determine the administrative mechanism within the Department that would carry on the actual legwork, so to speak, carry on this program, should the Congress see fit to enact it.

Mr. O'HARA. My only reason for making some of these questions is that I realize we have a practical and immediate problem. I do not want to create in someone the impression that I am necessarily going to follow the same idea in other fields.

The CHAIRMAN. Mr. Macdonald, did you have a question?

Mr. MACDONALD. Yes. I suppose I should make an apology first. The witnesses have been very cooperative and erudite. However, I do not wish to join with the others on both sides on commending the Public Health Service. I feel very strongly about this, because I have two young children, both of whom participated in the field test.

Unfortunately, at the height of all the hubbub, my wife made me make the decision as to whether they should have their other shot. Because I did not know, and because I did not know anybody here in Washington to get an answer, I canceled the test. Now I would feel

terrible, with the polio season coming up in the northeast section of the country, if something would happen to either of my children.

While my heart went out to you, with Mr. Priest's mention of the fact that you had to make this grave decision, there were many parents in our country who had to make a very important decision to themselves. It just seemed to me that all of this could have been avoided.

I hope you won't think I am unfriendly if I will ask some questions that will at least clear up in my mind how, perhaps, this whole thing could have been prevented.

I was wondering, as the doctor was taking us through the Odyssey of what happened, at the time you were conferring with the Canadian people at the Connaught Laboratories, how much cooperation there existed between the American Public Health Service and the experiments that were going on up there. Was there a close working relationship?

Dr. SEBRELL. There was, Mr. Macdonald. We have had very close relations with the Canadian people. The Connaught Laboratory is the laboratory that first worked on a large scale with the growth of the virus in tissue. As I indicated in my testimony, that was the first place we went a long time ago.

The minimum requirements that are being used, the standards being used by the Canadian Government today, we are told by the Deputy Minister of Health in Canada, are almost identical with ours. They are adopted from ours.

Mr. MACDONALD. They adopted their system from ours?

Dr. SEBRELL. That is right.

Mr. MACDONALD. I have to ask another question at that point: As I understand the Canadian system, they are doing it in a very different way. Is it not true that they are more or less government sponsored and in a nonprofit laboratory? Is not the Connaught Laboratory a nonprofit organization connected with the University of Toronto?

Dr. SEBRELL. In the case of the polio vaccine, the Canadian Government licensed not only the Connaught Laboratories, but also two American companies, Parke-Davis and Lilly.

Mr. MACDONALD. And they are taking serum from us?

Mr. SEBRELL. They were until we stopped them.

Mr. MACDONALD. How long ago were they stopped?

Dr. SEBRELL. Parke-Davis vaccine had been sent into Canada, had been tested and released by the Canadian Government, and was ready to be used when Dr. Scheele made his announcement on May 7 that all vaccinations were stopped. When they heard that up there they also stopped the use up there. They thought something was possibly wrong in the United States, and they had better stop the use of the Parke-Davis and Lilly vaccine up there.

Mr. MACDONALD. Do you know what price they were paying for our vaccine?

Dr. SEBRELL. No; I do not.

Dr. SCHEELE. I am sure it would be very close, if not identical to the United States price.

Mr. MACDONALD. Am I correct that the price that the Canadians are giving it to their children would be roughly only one half of what our costs are?

Dr. SCHEELE. I think our best information is that their vaccine is being sold at cost because it is produced in a nonprofit laboratory. We are not real sure of their cost, but it is something over a dollar.

Mr. MACDONALD. What is our cost?

Dr. SCHEELE. Well, our cost here averages around $2.60 to $2.80. Eighty cents a cc. is a good average price. It depends on the size of the container. You see, a large part of the cost of the vaccine is actually in the packaging. So if one packages in 9 cc., enough for 9 injections in 1 bottle, the cost of that bottling is not much more than putting 1 cc. in a single bottle. This makes quite a difference.

Mr. MACDONALD. If I could interrupt you, sir, that is probably true. But I do not quite follow why the Canadians in taking two of our sources still were able to charge less than half of our price.

Dr. SCHEELE. No, my reference to cost in Canada was related to what it was costing from Connaught, not what it was costing from the United States manufacturers.

Mr. MACDONALD. I thought the figure you were giving me and the figure I asked for was the average total cost?

Dr. SCHEELE. No; we do not have that information. We can try to get it for you.

The CHAIRMAN. Will the gentleman from Massachusetts yield for a second?

Mr. MACDONALD. Certainly.

The CHAIRMAN. I intend to ask permission to insert into the record today at the close of the hearings a study of the Canadian program which we asked the Congressional Library to prepare. I had just noticed it as the gentleman was proceeding with reference to cost.

It gives the figure here that the federal and provincial governments from the Connaught Laboratories purchased the vaccine at $1.50 for three shots, and that the commercial cost was $6. There is a great deal of information there. I call it to your attention as you may wish to study it in the record further. It has been prepared by the Legislative Reference Service of the Library of Congress.

Mr. O'HARA. Would my colleague yield to me?

Mr. MACDONALD. Yes.

Mr. O'HARA. I am interested in this very much. I hope, Mr. Chairman, we may explore a bit into this cost situation.

Dr. SCHEELE. May I make a comment on the cost? It would be difficult and probably not too objective to compare costs. Connaught Laboratories is making this on a small scale. To make it on a larger scale that some of our American industry is making it requires a rather extensive outlay of funds in the purchase of rather large-scale equipment.

For example, one United States manufacturer is making single lots of vaccine twice or three times as big as the total output of Connaught Laboratories up to 2 or 3 weeks ago. This means rather elaborate stainless steel tanks, pipes, and things. You have a different cost factor. Just to take a sale price may lead to wrong impressions. I just wanted to raise that point.

Mr. STAGGERS. Would the gentleman yield for another point?

Mr. MACDONALD. If they are making it in small lots, am I incorrect in feeling that they are current with their supply? Is the supply and demand in Canada fairly current?

Dr. SCHEELE. No, sir. The purchase financed 50 percent by the Canadian Ministry of Health was for enough to immunize 500,000 children, and these children were to be largely taken care of in much the same way as that used by our National Foundation for Infantile Paralysis. They were to be in the first and second grades throughout the Provinces, although Quebec altered the plan and decided to do the 2-year old children. I don't know why that happened. Maybe they had a higher incidence of polio in the 2-year-olds.

Mr. MACDONALD. It was my understanding that there was no hubbub, no soap opera thing about this in Canada. After conversations with you they adopted the American methods, as you just stated, set up a plan for distribution, and stuck to that plan. There has not been, to my knowledge, one headline, one controversy or a name calling. There has been nothing. It has been a straightforward, ordinary, usual distribution procedure. Am I incorrect?

Dr. SCHEELE. The Canadian Government set up a grant-in-aid program in which the Government agreed to furnish 50 percent of the cost if the Provinces were willing to put up the other 50 percent. It is really the Provinces that are buying the vaccine with the assistance from the Canadian Government itself, the National Government.

Mr. MACDONALD. And a Province would correspond to a State here?

Dr. SCHEELE. Yes, sir.

Mr. MACDONALD. And that system has been in effect since the announcement date, has it not?

Dr. SCHEELE. Yes, sir; it has been.

Mr. MACDONALD. Do you not think we could have profited by that? I do not quite see if the Canadians used our research facilities and took our serum, why they are so much ahead of us, and why they have been able to have a smooth operation when we have not.

Mr. PERKINS. I would like to make one comment, Mr. Macdonald. That is that I think the position of the National Foundation for Infantile Paralysis here—I don't know the exact position it was in up there—is a factor that is frequently overlooked in the discussion of this problem. The NFIP stood ready on April 12, and had already contracted for the bulk of the output of these manufacturers, and had laid out a program of doing the first and second graders.

So to all intents and purposes the United States national program was the NFIP program, and that program has proceeded on an orderly basis. To put the thing in its proper perspective it would seem what we are considering is the program to take effect immediately upon the completion of the NFIP program. That is the basis of the Secretary's report to the President.

In other words, the reason why a Government-operated or Government grant-in-aid program is not in effect here is that the total output of the manufacturers is being devoted to the completion of a free 100 percent immunization program conducted by the National Foundation for Infantile Paralysis and for which contracts were made prior to April 12.

Mr. MACDONALD. The only comment I have to make about that is that it should have been done earlier. As I said, my two children were in that program, and are now out of it. There has been a controversy in the homes of our country. I can guarantee you that from the homes in my own district. I do not think it has been quite orderly. That is my basic thing.

Where the National Foundation for Infantile Paralysis went along, it was fine as far as it went; but it seems clear to me and was clear to the Canadians, apparently, that it would not be restricted to two grades in school. If my child was in the third grade or the fourth grade or the fifth grade, I would like to have that serum available to me.

The Canadians realized that, and it seems to me—and I do not mean this in an offensive way—that we did not. I am trying to find out why.

Mr. PERKINS. Mr. Macdonald, the program has been before you.

Mr. MACDONALD. Yes, but this is May 27.

Secretary HOBBY. There is still no vaccine other than that. That is our trouble.

Mr. MACDONALD. Excuse me?

Secretary HOBBY. There is still no vaccine that can go out other than that to the National Foundation. I am not up to date on the recent figures, but I think they first contracted for some 27 million, and then cut it to 18.

Because of the production problems that we have encountered, I do not know how many million we have yet to go before the Foundation's free immunization program for the first and second graders can be completed. Hopefully, the day that is completed, some legislative program can go into effect on a priority group taking the children right on through.

Mr. MACDONALD. Mrs. Hobby, you undoubtedly know a lot more about it than I do, I certainly hope so, and I am not questioning what you just said. I have no way of judging how much the difficulty with the Cutter Laboratory held up your program. But even without that difficulty, there is no plan even as of now for the distribution of that that I have heard of.

It seems to me it is a late date to be in here on this program when, at this time, we have the community child bureau, whereby you do not need any legislation to have the Congress appropriate funds to give this serum to this already-set-up department so that they can give out these vaccinations against polio the same way they do against smallpox and the other diseases that have been mentioned here this morning by the doctor. I do not quite see why you had to wait.

If somebody came before the Congress to appropriate money for such a worthy cause, I am sure it would be in and out of the Congress in 1 day. Nobody has come before us for those funds.

Is it not true that the funds could be asked for by your Department to be given to that community health service, the Children's Bureau?

Secretary HOBBY. I am sure we could. I don't know, Mr. Macdonald, whether you have read the report to the President. I wouldn't blame you if you hadn't as it is rather long.

Mr. MACDONALD. Without being at all offensive, I am not terribly interested in reading the report. I am interested in getting the vaccine flowing in a steady channel to the children.

Secretary HOBBY. If I may reply to the gentleman, the report to the President does show how the best minds that we could put upon it recommended that we use to get safe vaccine to the children of the United States as quickly as possible. That was the only reason I mentioned the report to the President.

I know it is a confusing picture to you as a father, and to many people. Much has been said and written that is of a confusing nature. I do not take it offensively at all, believe me.

I think, if I may interrupt myself a minute, that the production estimates have been one of the most confusing pictures in the United States. I am sure Dr. Scheele and Dr. Sebrell have told you that there is a very great difference between a manufacturer's production estimate and a vaccine that actually goes out. I am sure you heard also this morning the chronology of what actually goes on in the testing and making of a safe vaccine.

I believe that you have here a plan which will get the vaccine to the children of the country faster than any other way you could do it. You have in every State now, as you well know, State health officers, city health officers, county health officers, who are accustomed to doing these things. It seems to me that it is just best to use the machinery and the people that you have there now doing it, rather than trying to set up some new and complicated way.

I must say, and I hate to again refer to the report, the eagerness and the willingness with which the governors of the United States assumed their responsibilities, and also the State and Territorial health officers, left no doubt in our minds that those were the best channels and the fastest channels to use.

Mr. MACDONALD. I can only pray you are right, Mrs. Hobby. I hope it turns out well in the long run. I am sure we all feel the same way about that.

Mr. STAGGERS. Would the gentleman yield?

Mr. MACDONALD. Yes.

Mr. STAGGERS. Do you have the information on how much vaccine has gone to Canada?

Dr. SCHEELE. 13,930 three-cc. vials. In other words, that would be enough for 39,000 single injections, or the full three cc.'s for 13,000 children.

Mr. STAGGERS. Are there any countries besides Canada that have received any of this vaccine, sold, shipped, or otherwise?

Dr. SCHEELE. I think possibly on the first day or the second day after the release of the vaccine, a small shipment was sent to Mexico. This was before the export controls were placed on it. As far as I know, that is the only vaccine that has left the United States.

I don't believe export controls, however, affect Canada. I mean we work differently with Canada in the export of all materials than we do, necessarily, with other countries.

(The following information was later supplied:)

Information obtained since the testimony indicates that a total of 93,393 cc.'s of poliomyelitis vaccine was sent for export to foreign countries by Parke-Davis on April 12. Six thousand cc.'s were designated for Sweden, 6,000 for Cuba, 6,000 for Mexico, 3,000 for Panama, and 450 cc.'s for Jamaica. On April 13, however, the Department of Commerce placed export controls on the poliomyelitis vaccine, and it was possible to recover all but 21,450 cc.'s designated for export.

Parke-Davis had also shipped 41,790 cc.'s (13,930 three-cc. vials) of the vaccine to Canada (not subject to export control) which had been released for such shipment by the National Foundation for Infantile Paralysis. All but 5,300 cc.'s were administered, and this amount has been returned to Parke-Davis. Further shipments to Canada must also be cleared by the National Foundation for Infantile Paralysis.

Mr. STAGGERS. Dr. Scheele, do you have the amount that was shipped to Mexico?

Dr. SCHEELE. I may have that here.

I do not have it. I thought I did. It seemed to me it was something like a few thousand cubic centimeters. It was some very small quantity.

Mr. STAGGERS. Are there any regulations or controls that can stop these sales, or have they all been stopped?

Dr. SCHEELE. The manufacturer must request approval for shipment abroad, then the Department of Commerce must issue a license for shipment abroad. They have not, to my knowledge, been issuing such licenses.

Secretary HOBBY. That is correct.

Mr. STAGGERS. Then I understand there has been none of this vaccine shipped or distributed any place in the world from the United States except to Canada and Mexico?

Dr. SCHEELE. And some very small quantity sent to some United States nationals abroad.

Mr. ROGERS. Do you think it would be in keeping with good governmental policy if we should adopt a regulation that would put a firm control on the person to whom these laboratories sold this vaccine? As I understand it, there is nothing to prevent them at the present time selling this vaccine to whoever they wanted to contract with for it; is there?

Secretary HOBBY. No, I suppose there is nothing that would prevent them.

Mr. ROGERS. In other words, if they should decide that they did not want to sell at all to the national foundation, they could sell it to different doctors?

Secretary HOBBY. Mr. Rogers, I think you would be interested in this, and I know the other members of the committee will.

I think it was on April 21 when representatives from all of the manufacturers were in, and each of them individually pledged himself to ship the output of that factory on the basis of a voluntary allocation plan. That is, going back to the 5 to 9 child population, each State, for example, would receive its pro rata of the available vaccine for its 5 to 9. The State health officer then would pass this on to the Department and the Department, in turn, would tell the manufacturer where to ship. So each State would then get its fair share of the available vaccine. They have all pledged themselves to ship in accordance with such a plan.

Mr. ROGERS. Do you have any figures on how much has been sold commercially?

Secretary HOBBY. Yes, sir. I think it was around 600,000 cc. I will let the scientists and doctors pick up there, because there is a name of a medicine in here that I can't remember.

But at one time the six manufacturers thought they could have fulfilled their contracts to the national foundation earlier. When that was true—I hope I am correct in saying this—when that was true, then some 600,000, it seems to me it was 660,000 cc. were released in commercial channels. That was the vaccine that people heard spoken of as vaccine in the black market. It was not vaccine in the black market. It was vaccine that had been sold by the manufacturers to normal drug outlets over the United States.

Since April 21, no vaccine has been sold or shipped in so-called normal commercial outlets. It has all been going to the foundation for the first and second graders.

Mr. ROGERS. Thank you.

Mr. MACDONALD. I just have one last question. In the Canadian use of the vaccine, there have been no fatalities that have been traced back to the vaccine in Canada, have there?

Dr. SCHEELE. As far as I know there have not been. Also, polio hits Canada much later than here.

Mr. MACDONALD. In the method of testing that they use in Canada, they use a different, more complete system than we do, do they not?

Dr. SEBRELL. No, they use the same tests that are used here. They don't handle them in exactly the same way.

Mr. MACDONALD. Here do we not examine merely the protocol, the slip that is handed over by the manufacturer to the Public Health?

Dr. SEBRELL. That is right, with check tests. We do check tests in the Government laboratory. But we do not test every lot.

Mr. MACDONALD. In Canada, do they not use the double-test method? First it is checked by Connaught and then it is checked by the Canadian Health and Pure Food Department?

Dr. SEBRELL. There are two kinds of tests. One is done on tissue culture and the other is done on monkeys. In Canada, the government does a tissue culture test on every lot, and they require the manufacturer—they do not do a monkey test—they require the manufacturer, however, to send them the slides made from the monkey's spinal cord so that the Government itself can examine the slides.

Mr. MACDONALD. Since it proved there that they have had no fatalities and we have had a great number, do you not think perhaps we should go back to the original system that was used at the time of the field test, of the triple testing?

Dr. SEBRELL. No, I do not think that would be advisable. I believe we get better safety by the rules we have adopted of improving the test rather than multiplying the test. It is the sensitivity of the test, not the number of times you do the test.

Mr. MACDONALD. The thing that struck me when you were going through that was that at the time there were only 400,000 children involved we triple checked, and when it got to 5 or 6 million we spot check. I do not follow the logic of that change.

Dr. SEBRELL. The triple check was not done only for safety purposes. The triple check was also to enable the three laboratories to gain experience. The added safety provided thereby was a dividend, you might say.

Mr. MACDONALD. Do you not think, sir, that if you did still have this triple test that the Cutter tragedy would never have occurred?

Dr. SEBRELL. No, I do not think that would have had one bit of effect. If the test itself is not sensitive enough, it does not make much difference how many times you multiply. If the test is no good, if you do it a dozen times it does not make it any better. It is better to make the test better and then do it properly.

Mr. MACDONALD. You think it is merely coincidence that in Canada, with this test, there are no fatalities, and with us having a spot check we have had a number of fatalities. Do you think that is mere coincidence?

Dr. SEBRELL. If I could add one more point, that they have injected maybe 500,000 children in Canada, and in this country, even with 1 manufacturer's product twice that many have been given with no trouble at all.

Mr. MacDonald. Thank you.

Mr. Hinshaw. I just wish to point out that the area in which the Cutter vaccine was sent was one of the higher incidence at that season anyway. It could be expected that more cases would develop in San Diego, Calif., which is in the south, than there would be in Saskatchewan, for example, in the far north, because it is still winter up there in April.

Dr. Scheele. You raise another question about differences. The Canadian Government has them send it slides of the spinal cords and brain tissues of the monkeys. We would not gain a great deal from that in the United States, because our manufacturers send them to the man who has great experience in reading them under the microscope as anyone in the world, Dr. Bodian. These do not represent any real differences in this particular situation.

I would like to point out something which Dr. Sebrell did not bring out, and on which we are going to try to write a scientific story, we hope this weekend, if we can find time enough to get our pencils out and get them sharpened. That is that there is a false impression gained in the second person test. The important part of the testing is the testing that can be done, that must be done, in the plant. This is the testing which is done during and after the period of inactivation. What is done here in making this vaccine is that the vaccine is grown on monkey kidney cells in test tubes. There are three strains of virus, type 1, type 2, and type 3. Small lots of each of those are grown. Bottles of the virus of type 1 are pooled, type 2 is pooled, type 3 is pooled, to make larger quantities. Then formaldehyde is placed with each of those separate pools, so that the total strength of that solution is one four-thousandth. This is held at about 36½° to 37½°, somewhere in that range, of temperature, over a period of days, and during this period of time, held at that temperature, the virus inactivates. It loses its ability to infect monkeys, to infect and kill cells in tissue culture, to infect man.

Certain tests are done in the course of that inactivation period to determine whether or not it is inactivated. In other words, you know how much virus you start out with, you test that, and then you discover you have less virus that is active, and still less virus that is active, and at some point you come to the baseline where your tests show you have zero active virus. Normally this requires 72 hours. Then, under Dr. Salk's process, one carries this cooking process, although that is not high temperature, that is body temperature, one carries this process beyond the baseline, and it is the tests done after it goes below the baseline that are the critical tests in the whole process and in assuring us safety.

At the end one can do some sample testing. As Dr. Sebrell pointed out, unless you tested every cubic centimeter made you would not have absolute security. Also, it is conceivable that accidents can occur in filling some vials which would never be picked up on sampling at the end unless you just happened to hit it. Say there were two vials that were contaminated, and if you got one of those vials for a Government test later, yes, one might pick it out. But here, again, the tests there that are important, and the thing upon which the greatest reliance is placed by the men who are watching this process, is the virus activity during inactivation. It is those tissue-culture tests that are the critical part of this process. It is around those that our deliberations of the

last several weeks with the outside scientific advisers and the manufacturers have revolved. It is essentially around the interpretation of the results in that inactivation process that our so-called revised standards just developed, as a result of experience, experience which we would not have had had it not been for large scale production and the passage of time. And possibly we would not have been aware of it had it not been for the Cutter incident.

Mr. MACDONALD. Incidentally, at those conferences I hope it is not a collective bargaining session, and I hope that it is public health telling these manufacturers what to do.

Dr. SCHEELE. If you read the newspapers, I think you will discover, perhaps, that we told them, because some of them were a little worried about some of the testing on some of their processes. But I think when we went into our second day of discussion with them, and the night of discussion yesterday, and as we worked with the interpretation of the revised standards in relationship to the technique and the work of any given manufacturer, and each one has little differences in the way he does these things, some do them in big containers and some in small containers, and they have other variations. They all came into agreement.

They all found that with the revised standards their processes could be adapted. In some instances, one item that we are changing or revising the interpretation of, they were ready to change, but in others they were not at first. So we presented standards, and we now have a hundred percent agreement. All six firms agreed that they will comply with these, and our vaccine committee made it very clear to them, and the Public Health Service staff made it very clear to them, that each lot of this vaccine must fit into it before it is going to be approved. As it is approved, we will have the best scientific judgment that the United States can put on this. This does not give 100 percent guaranty, but it gives an awful lot more guaranty than just living without being vaccinated does to the kiddies of the country.

There is a far greater risk of incurring polio if we do not vaccinate than if we vaccinate including even the experiences to date with vaccine which has caused problems.

The CHAIRMAN. Mr. Hayworth, do you have any questions?

Mr. HAYWORTH. Mr. Chairman, we have kept these people a long time. There are some questions I would like to ask, but I will yield to your judgment.

The CHAIRMAN. Well, I know there are a great many questions. I also know that these people have been up all night. It was the intention of the Chair, after we heard from the foundation and other witnesses, to ask the members of the Department to come back and report on developments during that time and give us a chance for additional questions. I can assure the gentleman from Michigan if he desires to yield at this time that he will be given recognition at that time.

I do not want to foreclose any questions, but I am aware, as you are, that it is a little fatiguing.

May the Chair ask unanimous consent at this time to insert into the record this study made by the Library of Congress on the Canadian system and how it has operated.

(The study referred to follows:)

THE LIBRARY OF CONGRESS,
LEGISLATIVE REFERENCE SERVICE,
Washington 25, D. C., May 24, 1955.

CANADA'S ANTIPOLIO SALK VACCINE PROGRAM

INTRODUCTORY NOTE

Canada made important contributions in the research leading to the discovery of Salk vaccine. For several years Connaught Laboratories at the University of Toronto has supplied the bulk of the virus used by American researchers in developing Salk vaccine. Dr. Raymond Parker and his associates at the Connaught Laboratories are credited with playing a major role in making mass production of vaccine possible through their development of the pure chemical medium in which polio virus is grown for inoculation purposes. Their work was financed by the Canadian Foundation for Poliomyelitis. They reported their findings just as the National Foundation for Infantile Paralysis was preparing to finance a project designed to find a way to produce the virus in quantity.

In addition to these scientific contributions, Canada participated directly in the extensive international field trials last year. Children from three Canadian provinces—Alberta, Manitoba, and Nova Scotia—received trial injections of the vaccine.

The confusion in the United States over public policy with regard to polio vaccine has inevitably led to comparisons of our experience with Canadian experience. As early as May 10, 1955, the columnist Walter Lippman commented, "There should * * * have been no more doubt here than there has been in Canada that the public authorities were in control." A Canadian newspaper, the Ottawa Citizen, reported on May 11, 1955, that some United States public health officials were privately commending Canada's decisive handling of the vaccine safeguards and its distribution. More recently, a United States Senator delivered a speech on the floor of the Senate commending the Canadian program.

The following report attempts to outline the major provisions of the Canadian antipolio Salk vaccine program, from its inception to the present date. Canadian newspapers have been the major source of information, especially the Toronto Daily Star and the Ottawa Citizen. In addition, a copy of the statement on Salk polio vaccine delivered by the Hon. Paul Martin, Canada's Minister of National Health and Welfare (on April 12, 1955) was obtained from the Canadian Embassy in Washington, D. C.

ORGANIZATION OF THE CANADIAN PROGRAM

Last fall, almost simultaneously with the inception of the independent evaluation report conducted by Dr. Thomas Francis, Jr., the Canadian Federal Government began making plans for the production of vaccine. Several reasons were given by the Hon. Paul Martin, himself a victim of polio as a child, for these early plans. For one thing, Canada's polio season, like ours, begins early in the summer, usually rising to a peak in August and declining rapidly in late autumn. "Immunization must therefore be completed prior to July 1 in order to anticipate a potential epidemic," cautioned Mr. Martin. Canada's worst epidemic occurred in 1953 when more than 8,700 cases were reported, killing more than 400 and leaving almost 5,000 afflicted with some paralysis.

An equally important reason for making early plans, cited by Mr. Martin, was the factor of time involved in producing, testing and administering the vaccine:

"Because of these considerations (polio season and 5-week period required for administering shots) and the fact that the production and testing of the vaccine is a long and complicated process extending over several months, the Government decided last fall that, although the effectiveness of the vaccine had not yet been conclusively established, no time should be lost in making plans for the production of vaccine so that substantial quantities might be available for this year's polio season.

"Accordingly, arrangements were worked out, in cooperation with the 10 Provincial governments, under which the Federal and Provincial governments would share on a 50-50 basis the cost of underwriting the production of the vaccine at the Connaught Medical Research Laboratories. As a result, sufficient supplies are already available in Canada to immunize more that 500,000 children in selected early school-age groups under the active direction and supervision of Provincial and local departments of health."

Financing of this program was arranged on a 50–50 basis between the Federal and Provincial Governments with payment going to Connaught Laboratories which produced the vaccine in this year's program. This type of joint financing is a departure from ordinary procedure in that the costs of immunization programs are usually borne by the provinces and municipalities. It was decided, however, that the experimental nature of the Salk vaccine program and the large quantities of vaccine involved necessitated Federal sharing of the financial burden. Major credit for this decision goes to Dr. Robert D. deFries, director of the Connaught Laboratories. In May 1954, about the same time that the National Foundation for Infantile Paralysis held its initial meeting with 11 major pharmaceutical houses (including the 6 which subsequently decided to manufacture Salk vaccine), the Dominion Council of Health met in Ottawa. At this time, Dr. deFries, confident of the vaccine's effectiveness, recommended that the Government underwrite the cost of production of the vaccine.

Accordingly, the Federal and Provincial Governments last year made grants in the amount of $750,000 for the purchase of enough vaccine from Connaught Laboratories to inoculate 500,000 children. At the time Dr. Francis made his evaluation report at Ann Arbor, Mich., on April 12 this vaccine had already been distributed to the 10 Canadian Provinces. An editorial in the Toronto Daily Star for April 12, 1955, commends the joint governmental action in 1954 as follows: "Nearly half a million Canadian children will receive Salk vaccine this year, because Federal and Provincial health authorities wisely risked $750,000 on a favorable test result." In addition to its share of $375,000 granted for vaccine production, the Government of Canada last year spent $125,000 for polio research. Prior to last year, the Canadian Government had made more than $1,500,000 available to the Provinces under the national health program for projects of various kinds directed toward the control of polio. In addition to substantial sums provided for gamma-globulin production and for research into its value, these grants were used for the purchase of respirators and other therapeutic equipment; the establishment of polio clinics and suitable hospital accommodation for polio victims; the employment of special professional staff for training and rehabilitation; and the encouragement of research on polio problems.

The Federal Government is continuing the 50–50 cost-sharing arrangement this year. In the words of Mr. Martin, on April 12:

"In order to help stimulate the widespread use of the vaccine, I wish now to affirm that, in addition to the assistance provided last year toward the purchase of the necessary supplies for the immunization of 500,000 children, the Federal Government is prepared, under the terms of the national health program, to share on a 50–50 basis with the Provinces the cost of purchasing additional polio vaccine for distribution during the present year. This, we hope, will provide the most effective means of encouraging an increase in the supply of the vaccine produced and utilized throughout Canada."

It is not known how much the new Federal policy will cost, nor exactly how much vaccine can be produced, but estimates are that it may mean increases of as much as $1 million toward production and distribution of Salk vaccine in Canada.

Clearly, therefore, Canadian officials foresaw as early as the summer and fall of 1954 that there would be tremendous demand for Salk vaccine to prevent another epidemic year like that which occurred in 1953.

PRODUCTION OF SALK VACCINE

While production is concentrated at Connaught Laboratories, the Institute of Microbiology and Hygiene at the University of Montreal subsequently moved from experimental use of the vaccine into limited production. It is expected to produce 200,000 complete doses of vaccine by July 1. The only other source of vaccine in Canada at the present time are the Canadian branches of two American drug manufacturers. Parke, Davis & Co. have a Canadian sales branch at Windsor, Ontario, and Eli Lilly Corp. have a branch at Toronto. Both firms were licensed by the Canadian Government on April 12, 1955, to produce and distribute Salk vaccine in Canada. No commercial vaccine, however, is used in the Government's program. Sale of such vaccine is permitted by private drug houses, to be administered to patients by private doctors. In a full-page advertisement inserted in Canadian daily newspapers on April 12, Parke-Davis & Co. reported that its supplies would be available for children to be inoculated by their own doctors rather than by local boards of health.

Dr. Mackinnon Phillips, minister of health for Oontario, stated on April 12 that Connaught Laboratories plans to farm out the manufacture of the vaccine to

six private Canadian drug houses "in the next few months." He predicted, therefore, that after next September the free supply of the vaccine would be sufficiently increased that there would be no problem of immunization.

The combined production of the Connaught Laboratories and the Institute of Microbiology by July 1, 1955, is estimated at 1 million complete doses: 800,000 at Connaught Laboratories and 200,000 at the Institute of Microbiology. Connaught Laboratories expect to produce enough vaccine to inoculate 2 million people within the next year. This is almost 40 percent of the total of 5,100,000 children under 16 years of age in Canada. It has been estimated that it may be 2 or 3 years before all of the 5,100,000 children will be inoculated.

There have been some rather controversial statements by drug-company spokesmen as to their capacity for production. In the Toronto Daily Star for April 13, 1955, a leading pharmaceutical firm (unnamed) announced it could saturate the commercial vaccine market within 90 days. Other authorities are reported to have expressed some skepticism at this probability.

COST OF PRODUCTION

The Salk vaccine purchased jointly by the Federal and Provincial Governments from Connaught Laboratories costs $1.50 for the complete course of 3 shots. It is then administered free to eligible children whose parents have given their consent to have their children inoculated by public health authorities.

By way of contrast, commercial vaccine costs $6 for the 3-shot vial plus the physician's fee. On April 25, 1955, the Hon. J. J. McCann, Minister of National Revenue, announced in the House of Commons that commercial vaccine would not be subject to the 10-percent sales tax, which would have run the cost up to $6.60.

ALLOCATION AND DISTRIBUTION OF SALK VACCINE

Under the plan the Federal Government sees that Canada's domestic Salk vaccine production is properly and proportionately allocated to Canada's 10 provinces according to population needs. From then on, the respective Provincial departments of health are entirely responsible for the distribution of the vaccine.[1] In this connection, however, the minister of health reported in his April 12 statement that:

"It is desirable * * * that there should be provincewide uniformity in the use of the vaccine. With this in mind, priority will be given to children in selected age groups, with those in ages immediately above and below serving as observed controls."

By and large, the Provincial governments earmarked their vaccine supply for distribution to grade 1 and 2 children. The one exception is the Province of Quebec, where health authorities decided to inoculate all 1- and 2-year-old children.

Half of the Canadian supplies of vaccine were distributed in Ontario, where the vaccine was used for the first time on March 4, more than a month prior to the historical date of April 12. According to Dr. J. T. Phair, deputy minister of health for Ontario, three-quarters of the 250,000 children to be inoculated in the Province had already received their first shots by the time Dr. Francis made his report.[2]

In other Provinces, the inoculation program was delayed, awaiting the official medical report. In British Columbia some 49,000 children began getting their shot April 18, 1955. In Alberta, enough vaccine was reported on hand to inoculate very grade 1 and some grade 2 pupils. The Saskatchewan Department of Health delayed starting the inoculation program until May but had enough vaccine to inoculate 30,000 schoolchildren in grades 1 and 2. Manitoba, which delayed its use of vaccine until the official medical report, launched its inoculation program on April 18, 1955. Quebec also awaited the results of the evaluation report before starting its program. It is important to note, however, that the preliminary steps had already been taken in each Province, the vaccine was on hand, the consent of parents obtained, and organizational details worked out in advance.

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[1] On May 9, 1955, however, it was reported that all United States-produced Salk vaccine had been barred entry into Canada until the United States Public Health Service recommended resumption of its use.

[2] Toronto Daily Star, April 12, 1955.

TESTING ARRANGEMENTS

In his initial statement on April 12, 1955, Hon. Paul Martin emphasized the safety factor in connection with the three-way testing of Salk vaccine in last year's international field trials and the necessity for maintaining the same standards in the continuing governmental program in Canada.

"Before being issued for last year's trial, the vaccine was thoroughly tested in laboratories, both by animal inoculation and by tissue-culture methods. Tests on each lot of vaccine were conducted in three laboratories and every possible precaution was taken to insure complete safety before any vaccine was released for use. The field trials have clearly confirmed this point. The vaccine for use in Canada is subjected to the same rigid safety controls. * * * During the past several months, under the authority of the Food and Drug Act, the Laboratory [of Hygiene in the Department of National Health and Welfare] has carefully retested supplies of the vaccine as an added safeguard before they are released to Provincial authorities."

On the day that the United States Public Health Service announced temporary withdrawal of vaccine produced at Cutter Laboratories (April 27, 1955) a spokesman for Connaught Laboratories reaffirmed that there was little chance of error in the manufacture of the vaccine in Canada, because of rigorous laboratory tests to which it is subjected before being released for use. Samples of each batch of vaccine are tested on monkeys and by tissuees culture methods. The vaccine is then tested by the Laboratory of Hygiene of the Department of National Health and Welfare, which must give its approval before the vaccine is used on patients. Consequently, the vaccine produced at Connaught Laboratories is subjected to 2 rigorous laboratory tests, 1 by the manufacturer and 1 by the Canadian Government, before it may be used.

When the United States Department of Health Education and Welfare first announced the postponement of further Salk vaccinations (May 7, 1955), Dr. G. D. W. Cameron, Federal Deputy Minister of Health, telephoned Dr. Leonard Scheele, United States Surgeon General, and then telephoned the deputy health ministers of each of the 10 Provincial departments of health. It was unanimously decided that adequate safety precautions had been taken in Canada and to continue the program without interruption. As of May 16, 1955, it was reported that more than 500,000 children had been inoculated without a case of polio being reported.[3]

On May 9, 1955, the Toronto Daily Star carried a news item to the effect that Canada had barred the entry of United States-produced Salk vaccine until the United States Government releases its ban on Salk vaccine. In this connection, it is significant to note some of the reactions of Provincial and municipal health authorities to the difficulties encountered in this country with Salk vaccine. On May 9, 1955, the Honorable McKinnon Phillips, Minister of Health for the Province of Ontario, said: "We were pressured by three Ontario cities * * * to bring in the United States vaccine, but we insisted all our vaccine must be tested by the Government and it would have taken from us the control necessary for this sort of thing. We cannot make tests after the toxoid is in the ampoules and that would have been the case if the United States material came here. It's a good thing we didn't bow to medical societies that wanted us to bring in United States-made toxoid and let it be used in Ontario."

Dr. J. T. Phair, Deputy Minister of Health for Ontario, said: "There is nothing wrong with the Salk vaccine made in Canada and we are continuing the mass inoculations according to program. Some 256,000 children have had their first shots without any ill effects and this is most reassuring. If there is anything wrong with any United States-manufactured vaccine, which is used only in that country, it might be from the manufacture. It also might be psychological in many cases."

Likewise, the medical officer of Ottawa in Ontario, Dr. R. A. Kennedy said: "In Ottawa we have administered the Salk vaccine to some 10,000 children in grades 1 and 2 of the public and separate schools, and in some private schools. There has not been a single incident of an adverse nature in that entire pro-

[3] It should be noted that the Ottawa Citizen, May 11, 1955, reported a case in Toronto after an 8-year-old boy was given his first shot of Salk vaccine. Dr. L. A. Pequegnat, city medical health officer, emphasized that there was no connection between the boy's illness and the vaccine. He said the boy was too ill to attend school on Tuesday before he was inoculated on Friday. He then became ill again on Saturday. The pattern in the United States vaccine-related polio has been for illness to set in about 2 weeks after first inoculation.

gram. Nor have I heard of one in the entire Canadian program reported on. In the United States where the trouble did develop—and all instances were in California [as of May 7, 1955]—they occurred some 2 weeks after vaccination. In Ottawa vaccination started on April 16, more than 3 weeks ago, and if anything was wrong it would have been apparent long before now. We are ready to proceed with the second vaccination series on May 12. Unless we receive orders from Government health authorities to halt it, then the second stage of immunization against polio will be instituted."

Dr. L. A. Pequegnat, medical officer of health for Toronto was equally confident of the Canadian vaccine: "We are confident there is nothing wrong with the Canadian Salk vaccine and are proceeding in all Toronto schools according to plan. We have already inoculated more than 20,000 Toronto children in the first and second grades and this week we will give shots to some 10,000 third-grade students for the first time and second shots to the lower grades."

Perhaps the most significant statement from our point of view was that made by Dr. Andrew Rhodes, director of research at the Hospital for Sick Children and a scientist who played an important part in the experiments which made Salk vaccine possible. He said: "* * * on the basis of information available to us there is absolutely no cause for alarm over the vaccine program in Canada—Canadian precautions are much more stringent than those in the United States." [4]

FLEXIBILITY OF CANADIAN VACCINE PROGRAM

In spite of the fact that organizational details of a comprehensive, intergovernmental vaccine program were worked out last fall, the program has shown itself flexible enough to permit change. For example, originally the program called for 3 shots to be administered at 1- and 4-week intervals, thus involving a 5-week period altogether. This is the time element mentioned by Mr. Martin in his statement on April 12. This pattern, however, had to be reconsidered in the light of Dr. Salk's suggestion that the system be changed to 2 shots given 2 to 4 weeks apart and followed by a booster shot 7 months later. It was not easy to make such an important change in a complex program like the provincewide administration of the antipolio vaccine in time for this year's polio season. Each Province had set up immunization machinery on the basis of three fast shots. Nevertheless, almost overnight, the new plan, which had the support of Canadian doctors, was substituted. Incidently, this decision to defer the third shot means that from 900,000 to 1 million children instead of the original 500,000 will be inoculated by the July 1 deadline.

ROLE OF CANADIAN DOCTORS

The role of private doctors in the Canadian Salk vaccine is one of voluntary cooperation with public medical officials. Shortly after the announcement at Ann Arbor on April 12, the Canadian Medical Association issued an appeal asking doctors to administer any vaccine that became available in commercial channels only to the most susceptible groups. The statement was reportedly prepared by the association to clarify uncertainties in the minds of the public as well as the medical profession. Reaction to this statement by doctors was reported in the Ottawa Citizen of April 16, 1955, as one of reluctance to act as arbiters of who should receive the vaccine.

ATTITUDES OF THE PUBLIC

No opposition to governmental control of the vaccine program has been reported thus far in the daily newspapers. The first case of public fear, however was reported in Aylmer, Quebec, early in May when several angry mothers surrounded the entrance to the townhall. It is believed that the demonstration was due to misunderstanding over the age groups of children eligible for immediate inoculation. As noted earlier, Quebec decided to inoculate 1- and 2-year-olds rather than first and second graders. Originally, Quebec authorities had thought there would be enough vaccine to inoculate all children from 3 months to 10 years. When the shortage became apparent the shift was made to 1- and 2-year-olds.

It is interesting to note the position taken by a spokesman for labor in regard to governmental versus commercial distribution of Salk polio vaccine. Mr. Gordon Milling, research secretary of the Ontario Federation of Labor, issued

[4] Toronto Daily Star, May 7, 1955.

a statement April 14, 1955, that: "As long as polio remains a threat to public health, its prevention must not carry a price tag, nor should individuals be given special access to the vaccine simply because they can afford to pay for it * * *. Regardless of who is to manufacture it, therefore, the purchase and distribution should be handled exclusively by the health departments of the various governments. This will insure the available supplies will be utilized with maximum efficiency and without cost to those in the greatest need of this protection."

BLACK MARKET IN CANADIAN SALK VACCINE

In recognition of the fact that even in a carefully controlled, intergovernmental program, a black market might develop as long as there is a short supply of Salk vaccine, the Federal Government in Ottawa made arrangements with the Provinces to squelch any such activity. In a statement in the House of Commons on April 20, 1955, Mr. Martin reaffirmed his belief that the Provinces would be able to deal effectively with any threatened black market in Salk vaccine. He said further that as a result of Federal-Provincial plans made last fall "there will be in Canada as great a measure of control providing for the availability of the vaccine as exists in any other jurisdiction in the world."

CONCLUSION

It is evident from a careful survey of newspaper reports and public statements of Canadian officials that Canadian experience with Salk vaccine has been considerably different from ours. In contrast with the reliance in this country on six commercial pharmaceutical companies for production of Salk vaccine, the quasi-governmental Connaught Laboratories in Canada produced all the vaccine used in the governmental program thus far. Whereas laboratory testing of the vaccine in this country is done only by the pharmaceutical companies with the United States Public Health Service checking only on the methods of laboratory testing used, in Canada both the Connaught Laboratories and the Federal Department of Health and Welfare make laboratory tests on the vaccine before it is used on patients. By way of further contrast, the cost of a complete set of three shots of Canadian vaccine, borne entirely by Federal-Provincial Governments, is $1.50, whereas prices in this country have been quoted as ranging from $4.20 to $4.50 plus doctor's fees. In contrast with the leadership exercised in this country by the National Foundation for Infantile Paralysis the Canadian Foundation for Poliomyelitis has played a relatively minor role described as one of fund-raising primarily. Perhaps the most striking and tragic contrast, however, is noted in the fact that as of May 24, 1955, 88 cases of poliomyelitis out of a total of between 5 and 6 million children inoculated under the National Foundation for Infantile Paralysis program have been reported in this country; whereas out of more than 500,000 children inoculated in Canada not a single case of serum-induced polio has been reported. In contrast with the Canadian program which was ready to go into high gear on the day the official medical report was received, considerable confusion as to United States policy with regard to Salk vaccine continued for some time after April 12. As late as May 23, 1955, an all-day conference of experts met with public-health officials at the National Institutes of Health (Bethesda, Md.) to discuss the future of the mass antipolio inoculation program.

MARGERY CLARK, *Government Division.*

The CHAIRMAN. I will also ask if the Department, if given sufficient notice, can appear again maybe at the conclusion of these hearings so that we can bring all questions up at one time.

Secretary HOBBY. We will be available at your call.

The CHAIRMAN. Very well.

The subcommittee is very happy to hear from Mr. Burnside, one of our colleagues, who is very much interested in the legislation pending before the committee. We will be very happy to hear whatever statement you have to make at this time.

STATEMENT OF HON. M. G. BURNSIDE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WEST VIRGINIA

Mr. BURNSIDE. Mr. Chairman and members of the committee, thank you for extending to me the opportunity of appearing before you today. The subject of these hearings is, in my estimation, one of vital importance to the health of our children, and I want to congratulate the committee, collectively and individually, for devoting its time to consideration of a poliomyelitis program.

I have read with interest accounts of the testimony of scientists before this committee. I hope that when these hearings have concluded, the evidence they have unfolded before you will show that science has prepared a vaccine that is safe to use now. Whether that fact appears or not, it is, in my opinion, our duty to ourselves, our children, and our country, to plan for a program whereby wide distribution and full utilization of safe vaccine can be assured.

Of course, we must make certain that the vaccine employed is absolutely reliable and safe for use. I do not for a moment advocate a makeshift plan designed for speed alone. We should, however, be prepared for any scientific eventuality, so that the program can proceed in an orderly fashion in accord with scientific developments.

I am sure that the members of this committee are familiar with the several bills which have been introduced to establish a Federal vaccine program. I have introduced a measure patterned after the bill authorized by the distinguished chairman of the committee and my good friend, Mr. Priest. I think the general plan it contains is satisfactory. At the same time, I have no doubt but that other plans are equally worthy, and perhaps one of them might better fit present circumstances. It is not my primary purpose here today to discuss the general plan of any proposed program. I am sure that the Congress will look favorably upon any measure which reasonably assures the availability of vaccine for all children.

I think, however, that whatever plan is adopted by this committee should contain a provision which I have included in my bill. It should provide Federal assistance for bringing children to central points for inoculations if vaccine is available to be used during a period when public schools are not in session.

In my own State of West Virginia, and I am not sure this same situation exists elsewhere also, there is a very serious problem in reaching children in rural areas when school is not in session. We have a mountainous State. Many parts of it are relatively inaccessible but populated. Our school system is centralized. Children are brought from rural regions to consolidated schools by bus. If inoculations are given during the school term, they can be given at the schools where all can be inoculated. In the summertime, however, the situation is completely different. Children in rural areas cannot walk to the places where vaccinations are being given, so they must be brought in.

If the responsibility for getting children to the vaccination center is left entirely upon their parents, the program, in my estimation, cannot be completely successful. In the first place, many rural families do not have automobiles to bring their children from remote areas or towns into the city. Of thse who do have them, most will be used by

working fathers during hours when vaccinations could be given. During inclement weather, it is most difficult to get come of our people out to main highways. There is large-scale unemployment in West Virginia and many people simply could not afford to bring their children into the city for polio shots even though it is so vital.

If, on the other hand, responsibility is left upon the States for transporting children, there is no more assurance of success. Declining State revenues have made it impossible for West Virginia to maintain adequately all of its State programs. It is quite possible that it could not afford to undertake such a project. If it did, the additional burden would only further increase the economic stress upon our schools.

As far as I am concerned, gentlemen, the only answer is Federal provision for transportation of children to be vaccinated during vacation periods. Unless we provide some Federal aid for cost of the vaccine and transportation of children to receive it, I do not think a vaccination program can succeed.

The CHAIRMAN. We appreciate very much the statement you made. I think that you have touched there on a matter of importance so far as the legislation is concerned—that is the transportation of children during the vacation period when they are not in school. In some areas of the country that is more important than in others. In areas of my own State I think that would be a rather considerable problem. That is in the mountainous area.

There is one other question that comes to my mind constantly in connection with the bill which I have introduced, and that is the question of how best to get around what we call the means test. Have you given any thought to that subject?

Mr. BURNSIDE. I have given some thought to it, Mr. Chairman.

The CHAIRMAN. I would assume that under the legislation a State agency in charge of a program should be able to work out a plan under which it would not be necessary to embarrass a child.

Mr. BURNSIDE. Or a family, too, Mr. Chairman.

The CHAIRMAN. Or a family. I will never knowingly and willingly report to the House of Representatives a bill that in my opinion would contain provisions that would cause embarrassment to children in school, or to their families.

Now it has occurred to me that in most communities they have handled that question very well with the free-lunch program and I would think that they would be able to do so with a board or a committee. Now, as I understand it, in the free-lunch program there is a committee set up that makes a determination and thereafter in the school-lunch program no child knows whether another has to pay for his lunch or is exempt because of financial conditions in the home. I would want to be certain in the bill you have introduced——

Mr. BURNSIDE. Which is very similar to yours, Mr. Chairman.

The CHAIRMAN. And along with your suggestion on transportation, I want to be certain that whatever program is authorized in this respect is not one that would subject a small child in school to any sort of embarrassment because of his economic condition or that of the family of such a child.

Mr. BURNSIDE. You are exactly right. In some of these communities I was thinking about the reason I added this transportation section is that in the summer months the buses are torn down and re-

pairs. Now, those buses in these areas are now in the process of repair. The schools have exhausted their funds for the year. You know the problem we have now in financing our schools around the country. In these areas, you have many of these people that just do not have the funds to get their children to these consolidated schools.

Now I wanted to say this: I was called up in this program and told that we had 37 clinics already set up, that doctors were giving their time and nurses were giving their time and we had the children at the clinics, and I got a call from West Virginia that the vaccine wasn't there, Mr. Chairman. There we had already brought them in, and the State had already brought them in, and had them there. The vaccine was not available. So the State has already gone to that cost of setting up this program. Then it fell down.

I was hoping that we could find some way, as you stated so admirably a few minutes ago, not to embarrass these people back up these hollows and back up these creeks in these mountainous areas.

The CHAIRMAN. I think I can assure you that before any bill leaves this committee to go to the floor, we will have found that solution. I shall labor on it until we do. I do not think it is too difficult to do the job, but I want to be certain that it is done.

Mr. BURNSIDE. In certain of these areas it is very easily determined that they are indeed under distressed conditions. We have some communities of twelve or fourteen hundred people and there are only a handful of people working. You might say that you can raise charity to handle it, but I find it very difficult to get food.

We have a very large number of our people on surplus food now in the State of West Virginia. That is due to many factors which you gentlemen are aware of. I feel sure the other areas have the same conditions.

The CHAIRMAN. Are there any other questions?

We appreciate your statement before the committee and you have been very helpful. I have one other question. The bill which I introduced calls for an authorization of $28 million. That subsequently has been changed to $35 million, or at least recommended to be $35 million.

I wanted to ask this question: If it became the decision of the committee to suggest that the appropriation be whatever may be necessary to meet the requirements of the States, would you think that that might be a sound approach. I mean, not specifically to allocate the $28 million or $35 million; but to leave it up to the States what they might require to carry out their program?

Mr. BURNSIDE. I have taken care of that in H. R. 6973. I think you have a copy of that bill.

On page 2, on the second line it says:

Such sums as may be necessary—

and then I have taken care of the approval and other things on page 5. That is in—

in carrying out the program set forth in the application of such statement approved pursuant to section 4, and to provide reimbursement to such State for transporting children to central points for inoculation pursuant to section 10 of this act.

I have taken care of that under section 10. It is largely your bill, with that exception.

The CHAIRMAN. I realize they are very similar. If there are no further questions, we thank you very much and we appreciate your appearance before the committee.

Mr. BURNSIDE. I want to thank you for the opportunity and for your kind indulgence.

The CHAIRMAN. The Chair sees Mr. Bennett of Florida present.

STATEMENT OF HON. CHARLES E. BENNETT, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Mr. BENNETT. Mr. Chairman, I appreciate this opportunity of appearing before you today to testify on H. R. 6286, the poliomyelitis immunization assistance bill.

I am glad that this assistance is going to be given by our Federal Government in this worthy field.

We in Florida have a problem which would make it difficult for us to cooperate in the program established by this bill unless there is an amendment to this bill.

This problem has already been explained in a letter to your committee signed jointly by both Senators and the eight House Members from Florida. In our letter, we ask the committee to adopt the following amendment to section 6 of H. R. 6286:

Provided, however, That any State which appropriates funds for the purchase of poliomyelitis vaccine which wholly or partially carries out the intent of this act, may use the portion of its Federal allotment, not needed to purchase vaccine in the amount intended, for reasonable expenses incurred in the administration of such a vaccine.

The difficulty is that the Florida Legislature, in its recent session, appropriating funds for the purchase of Salk vaccine for indigent children, and expectant mothers, failed to appropriate any funds for administering any free vaccine programs established by our new State law and by this bill.

Perhaps the State's failure in this was caused by an inability to ascertain what the form of probable Federal legislation might be.

Dr. Wilson T. Sowder, Florida State health officer, has told the Florida delegation in Congress that there will be some difficult problems in administering this program. Our problem will be the separation of the needy from those who can afford to pay.

He tells us that unless the Federal legislation permits the use of part of a State's share under this bill for administrative expenses, our county health departments will be forced to drop much other important public health work to administer polio immunization programs.

I submit that this amendment is needed to make the program established by this bill fully effective in Florida.

To the extent that the program is handicapped by insufficient administrative funds, there will be less assurance that the vaccine provided by the bill will actually be used for the people for which it is intended.

Although I have spoken of the particular problem of Florida, as far as I know this same problem may exist in all other States. In fact, in some States there may be not merely a problem of decreasing other health services, but possibly even a complete failure of a practical distribution of the vaccine unless some amendment is adopted as above described.

I may add in conclusion that this is a relatively unimportant amendment. It would not disturb your program at all, but might make it thoroughly 100 percent effective. I will appreciate the consideration of the committee of this proposed amendment.

I appreciate very much your allowing me to testify here late in the afternoon when I know you all have other problems on your mind.

The CHAIRMAN. Did I understand you to say, Mr. Bennett, that the Florida Legislature before it adjourned, did make an appropriation for the purchase of vaccine?

Mr. BENNETT. In substantial sums.

The CHAIRMAN. In substantial sums?

Mr. BENNETT. Yes, sir.

The CHAIRMAN. I have an idea that that is probably the exception among all of the States. A number of the State legislatures I think probably adjourned this year before the question of mass innoculation came up.

Mr. BENNETT. I rather think that is so. Very few of them did make that provision. Even ours made it available in a fund in a rush at the end of the session in a way which the State board of health feels may be almost entirely ineffective because they would have to bring to an end their pellagra program, the tuberculosis program, venereal disease program.

They would have to cut down on these well-established programs in a very dangerous way unless something is done in the field of administration.

The CHAIRMAN. We may be able to get some additional information very shortly when we hear from the representative of the State and Territorial Health Officers Association.

We appreciate your suggestion in this amendment. I think it is worthy of careful consideration.

Are there any questions of Mr. Bennett?

Mr. SPRINGER. Mr. Bennett, I did not get the full impact of your amendment.

Mr. BENNETT. The amendment sent me by the Florida State Board of Health is specific. I asked them to write me what they wanted. They sent it to me precisely.

After I read everything they said, I think it might be possibly worded more broadly and it would help them just as much and maybe help others who may have a similar problem. I am not so sure that this amendment is not sort of patterned to Florida's program. It says:

> *Provided, however,* That any State which appropriates funds for the purchase of poliomyelitis vaccine which wholly or partially carries out the intent of this act, may use the portion of its Federal allotment, not needed to purchase vaccine in the amount intended, for reasonable expenses incurred in the administration of such a vaccine.

It seems to me upon reading this and upon thinking about the whole problem that perhaps you would want an even broader amendment than that which would allow the use of these funds to a certain reasonable extent in administrative purposes even in regard to your Federal funds which would not be matched by State funds because you may find that you would make it very difficult to carry out this program in some States.

They may find obstacles in the use of funds which they have to run their health program.

There may be obstacles to them in the distribution of that Salk vaccine.

In addition to what the Florida delegation has recommended, which is what I have suggested here from the Florida State Board of Health, my study of the matter would lead me to think that it would be even better if there was some provision which allowed a reasonable amount of this to be used for the additional administrative expense required to carry on this program.

I don't think the State board of health should be allowed to use its money to carry on its administrative activities, but I think unless you make some provision in the law which would allow them to carry on some administrative work under this program you might find that the very most needy States might not be able to have the program at all simply because they could not call the legislatures back in to correct the existing laws.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Mr. Bennett. Your amendment will be given the consideration of the subcommittee. We will now hear our colleague, Mr. Bass of Tennessee.

STATEMENT OF HON. ROSS BASS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mr. BASS. Mr. Chairman, and distinguished colleagues of the Interstate and Foreign Commerce Commission, I come before you today hoping I may be of some assistance in the solution of the problem of national interest, the distribution of the Salk vaccine.

Let me begin by saying that I possess little scientific or technical knowledge of the medical profession, but I have been immensely interested in the new serum founded by Dr. Salk, and that is for the prevention of that dread disease known to us as polio. I am also deeply concerned about the problem of distribution to the public of this serum, that now faces our Nation.

With the help of the Department of Agriculture and the Department of Health, Education, and Welfare, I have complied facts and figures, and propose, because expediency is of essence, the following solution.

To begin with gentlemen, my proposal is based upon a program that is now in effect under our present school systems, and that is our lunch program, which may be found in title 42, chapter 13, sections 1751 through 1760, of the United States Code. This section of our code provides for national assistance to States for the school-lunch program, and a system of apportionment for each State to receive Federal aid therefrom based upon the number of schoolchildren in the State, and the need for assistance in the State as indicated by the relation of the per capita income in the United States to the per capita income in the State.

This is the basic law for Federal assistance to be granted to schoolchildren in order that they might obtain free lunches, and the amount

of assistance is determined by the commissioner of education of each State.

Under this program, each county, in each respective State, with its county board of education, either sets up a committee, or they investigate personally the conditions prevailing at each school, then they in turn submit to the commissioner of education the amount of students or children that are in need of help in the free-lunch program, who in turn acquires the responsibility of requesting from the Federal Government the amount needed in order to defray the expenses for the free-lunch program.

My points, which number three, in relation to the Salk vaccine are these, using my State of Tennessee as an example: (1) At present, in the State of Tennessee there are approximately 10 percent of the schoolchildren that now receive the free lunches under this program. According to the Department of Health, Education, and Welfare, there are approximately 700,000 children between the ages of 1 month to 9 years of age, of which approximately 350,000 of these are of school age or between the ages of 5 and 9. The remainder are of the ages of 1 month to 5 years of age.

Using the same basis as you would under the lunch program, approximately 10 percent of the 350,000 that are attending school between the ages of 5 and 9 would receive the free Salk vaccine shots, giving you a total of 35,000.

(2) The children between 1 month and 5 years of age who number approximately 350,000, and are too young to be in school, are therefore not under the county board of education's observation. Therefore, the county board of education could not, in itself, be the only determining factor to be used, but the board working in conjunction with the county health department could determine those who would fall in the category to receive the Salk vaccine shots. Using the previous stated basis of the free-lunch program, or 10 percent of the approximately 350,000 would give you a total of 35,000. This would give you the approximate total of 70,000 children in Tennessee who are of the critical ages of 1 month through 9 years, that would require the free Salk vaccine shots.

(3) To state further, Tennessee's population is approximately 2½ million people, which is approximately one sixieth part of the total population of the United States. Multiply 60 times 70,000 children in need of the free vaccine in Tennessee, and you will arrive at the figure of approximately 4½ million children in the United States needing the vaccine under a gratuity program. Then in turn, multiply 4½ million times $2.33, or the cost of 3 shots, the necessary amount to render the children immune to polio, and the results will be within the amount of money sought by the President of the United States.

The figures I have given you are approximates, but I believe if a program such as this is followed, and since the machinery has been set up by the free-lunch program, then I believe this will not only expedite this distribution, but will save the country money as well.

The CHAIRMAN. We thank you for your testimony, Mr. Bass.

Mr. BASS. Thank you, Mr. Chairman.

(The following table was submitted by Mr. Bass:)

UNITED STATES DEPARTMENT OF AGRICULTURE, AGRICULTURAL MARKETING SERVICE

TABLE VI.—*National school-lunch program—Comparison of free or reduced price meals with total meals served, by States, 1953–54*

State	Total meals served (1)	Free or reduced price meals	
		Number (2)	Percent of total (3)
Northeast:			
Connecticut	11,917,443	753,782	6.3
Delaware	2,146,953	96,696	4.5
District of Columbia	4,677,182	68,769	1.5
Maine	9,141,897	1,130,183	12.4
Maryland	26,238,604	1,624,010	6.2
Massachusetts	62,365,924	3,587,225	5.8
New Hampshire	4,204,951	367,596	8.7
New Jersey	18,518,524	1,574,892	8.5
New York	170,997,588	27,375,408	16.0
Pennsylvania	45,957,581	3,056,814	6.7
Rhode Island	3,354,287	88,037	2.6
Vermont	3,314,099	430,161	13.0
West Virginia	20,702,504	3,415,700	16.5
Area	383,537,537	43,569,273	11.4
Southeast:			
Alabama	47,444,375	4,318,827	9.1
Florida	40,915,867	2,364,548	5.8
Georgia	52,693,298	4,532,299	8.6
Kentucky	36,477,163	4,520,109	12.4
Mississippi	28,771,460	2,528,655	8.8
North Carolina	72,721,895	4,826,392	6.6
South Carolina	36,029,328	4,128,726	11.5
Tennessee	48,206,113	4,910,549	10.2
Virginia	39,980,209	3,475,079	8.7
Area	403,239,708	35,605,184	8.8
Midwest:			
Illinois	100,289,764	3,756,600	3.7
Indiana	38,263,565	1,573,132	4.1
Iowa	27,011,265	731,086	2.7
Michigan	67,712,059	5,036,614	7.4
Minnesota	34,699,708	1,860,296	5.4
Missouri	37,443,379	2,300,346	6.1
Nebraska	9,427,929	511,836	5.4
North Dakota	6,308,692	928,734	14.7
Ohio	60,822,842	2,065,497	3.4
South Dakota	4,056,815	571,509	14.1
Wisconsin	23,044,445	2,011,361	8.7
Area	409,080,463	21,347,011	5.2
Southwest:			
Arkansas	27,318,293	2,501,053	9.2
Colorado	11,042,609	582,167	5.3
Kansas	15,574,696	217,759	1.4
Louisiana	68,418,968	9,642,697	14.1
New Mexico	6,214,176	812,282	13.1
Oklahoma	25,481,745	2,845,367	11.2
Texas	66,895,615	5,066,722	7.6
Area	220,946,102	21,668,047	9.8
Western:			
Arizona	10,310,192	914,977	8.9
California	114,681,282	5,525,415	4.8
Idaho	7,273,495	357,435	4.9
Montana	5,017,870	313,406	6.2
Nevada	1,341,874	192,478	14.3
Oregon	15,637,041	501,850	3.2
Utah	9,942,983	365,681	3.7
Washington	22,610,341	878,075	3.9
Wyoming	3,028,084	142,999	4.7
Area	189,843,162	9,192,316	4.8
Continental United States	1,606,646,972	131,381,831	8.2

TABLE VI.—*National school-lunch program—Comparison of free or reduced price meals with total meals served, by States, 1953–54*—Continued

State	Total meals served	Free or reduced price meals	
		Number	Percent of total
	(1)	(2)	(3)
Territories:			
Alaska	369,090	90,570	24.5
Hawaii	12,923,927	735,894	5.7
Puerto Rico	40,757,104	40,646,455	99.7
Virgin Islands	706,008	486,019	68.8
Territories	54,756,129	41,958,938	76.6
United States and territories	1,661,403,101	173,340,769	10.4

The CHAIRMAN. Dr. Bergsma, the committee appreciates very greatly your willingness now to go into a discussion of legislation on behalf of the State and Territorial Health Officers Association. We are indeed indebted to you.

You may proceed in whatever manner you desire.

STATEMENT OF DR. DANIEL BERGSMA, COMMISSIONER OF HEALTH, STATE OF NEW JERSEY; VICE PRESIDENT, ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICERS

Dr. BERGSMA. I thank you for the opportunity to appear before this committee.

Our Associaion of State and Territorial Health Officers considered this bill in its executive meeting and suggested that wherever the word "immunization" appears in this bill, that it be changed to vaccination, because it is something more specific from a medical point of view.

The CHAIRMAN. It is difficult to know when vaccination has been given whether immunization has taken place.

Dr. BERGSMA. That is right. It may be that nature has already immunized a particular child when the child is vaccinated.

So we could know when the child is vaccinated, but we would have difficulty in determining when the child was immunized.

The same concept applies when the word "immunized" appears in the bill. We recommend that that be changed to "unvaccinated."

As a matter of raising the question, under "definitions," in section 10, item (2), there seems to be a question in our minds whether the Secretary of the Department of Health, Education, and Welfare would be able to obtain in adequate time from the Department of Commerce this information as of June 30, 1955.

We thought perhaps a rewording of that to allow for the latest available information and possibly other related information as the source of foundation for making the decision.

We have no specific change to recommend, but question the rigidity of that definition based upon June 30, 1955.

In terms of item (3), again under "Definitions," section 10, item (3), as worded, that would lead to problems because the national foundation offered a program of vaccination for some children in most

States last year and is offering vaccination again for some children in States and Territories this year, but the number of children or the proportion of children being vaccinated in any one State under that program is, we are finding, quite variable.

The problem remaining, therefore, to a given State when the national foundation program is over would not be a constant ratio as contrasted with the number of children in that State or any age group.

To avoid such difficulties, we suggest alternate wording something like the following:

The number of unvaccinated children means the number of such children reduced by (*a*) the number who were vaccinated against poliomyelitis in 1954, and (*b*), two-thirds of the number whom the Secretary estimates will receive vaccination under the current program of the National Foundation for Infantile Paralysis.

That is the end of that proposed definition.

We suggest in (*b*) two-thirds of the number because the current plan of the foundation is to provide only the first two doses and a third dose must be thought of in connection with all of those children during the period anticipated to be covered under this bill.

Those, sir, represent the specific suggestions that I came to make. I will be glad to try to answer your questions, if any.

The CHAIRMAN. May I ask you, Doctor: As a State health officer, and as a member of the State and Territorial Health Officers Association, do you consider it important that the Federal Government authorize and appropriate funds for assistance to the States in carrying out this program?

Dr. BERGSMA. Yes, sir; I do, because many States are at the moment not able to pass legislation or appropriations for funds for this purpose. Certain States, including New Jersey, which did pass such legislation, did so with the anticipation that legislation of this general character would be passed by the Federal Government and, therefore, the legislation passed in New Jersey was not thought of as supplemental to this and not as a complete substitution.

The CHAIRMAN. Now, Doctor, suggestions have varied on this legislation. There are some who consider that the Federal Government should take no action at all in this respect.

The bill we are considering is a bill which proposes to authorize an appropriation of $35 million for assistance to the States to assure that no child between the ages of 1 and 19 shall be denied vaccination because of inability to pay.

Then there is the other going all the way up the scale, the idea that the Federal Government shall make available funds to pay for the vaccination of every child between the ages of 1 and 19.

In that long range of ideas there are many different viewpoints.

Has the State and Territorial Health Officers Association taken any position with reference to the question of the extent of Federal participation in this program?

Dr. BERGSMA. No, sir.

As an association, we have not taken a position in regard thereto. We thought of it more as a socioeconomic problem, rather than one of technical, medical, or public health.

The CHAIRMAN. I think you are right in that respect, sir.

Are there any other questions?

I might have one or two later on, myself. But do other members have questions?

Mr. ROBERTS. Doctor, do you see any difference in this program here and in the programs in the past which the Federal Government participated in for the control of other types of infections or epidemics.

Dr. BERGSMA. Actually I would say that there are quite a few similarities. I do not at this moment recall the exact language of the other bills. I do not think they were quite so clearly tied down to inability to pay.

Usually they represented a group of diseases rather than a single disease, but there have been exceptions such as tuberculosis, so to that extent it is similar.

Mr. ROBERTS. Are you familiar with the fact that in past years in the Department of Agriculture there has never been any question about the fact that the Federal Government has appropriated millions for the control of hoof and mouth disease and diseases of cattle and swine and all kinds of animals? There has never been any question about that, has there?

Dr. BERGSMA. Apparently not, sir.

Mr. ROBERTS. What are some of the administrative problems that you think might face the States in carrying out this program?

Dr. BERGSMA. That would vary State by State.

May I give information about New Jersey at the moment as an example, not necessarily an average sample.

We currently have about 68 biologic supply stations scattered throughout the relatively small, geographically small State of New Jersey. Physicians know where they are and are accustomed to go there to pick up biologics which the State department of health makes available to them free. We do not make them available free for any and all persons, but it is commonly understood that they are free to be used by the physicians for all patients who cannot afford to pay for the vaccine and who nonetheless would like to be vaccinated.

We have had no complaints that I am aware of in at least 8 years—and I say 8 years because I have been State commissioner of health for only 8 years—during that time I know of no complaint either from physicians or from the public in regard to this system.

The physicians in our State have pledged themselves repeatedly to render service, medical service, to those who need it, regardless of their ability to pay therefor.

They have therefore worked out a plan, if you will, or a system in that if the patient or the parent or guardian of the child is able to pay the full cost of the material and the medical service of giving it, then the physician obtains the material through the usual commercial channels, let us say, a drug store. He provides it in the form of the material injected and he charges the patient for both the material and for his service.

If the patient cannot pay for all, the first thing that gets taken out is the cost of the material, which the physician then obtains from one of our biologic stations free, and if the patient is not able to pay for all of the medical service portion of the cost, then that in turn is reduced to a point sometimes of zero, but an arrangement made between the patient and a physician.

I would judge that this system would work quite well in this situation in New Jersey. I would anticipate that we would have minimum need for what might be thought of as mass immunization clinics in order to achieve this program in terms of its application.

Mr. ROBERTS. In other words, you feel that it could probably be handled pretty much with your present setup?

Dr. BERGSMA. Yes, sir.

Mr. ROBERTS. Does the State of New Jersey require any kind of means test or certificate of inability to pay or anything like that?

Dr. BERGSMA. No, sir; not in terms of any such medical program in the provision of vaccines for this type of program.

Mr. ROBERTS. Is that pretty well left up to the physician?

Dr. BERGSMA. Yes, sir. If he says it is needed, we provide it free.

The CHAIRMAN. Doctor, the formula for the allocation of funds in the pending bill is a formula, as I recall it, that is based on the cost of the vaccine, multiplied by 20 percent of the unvaccinated population of the States multiplied by the States allotment percentage and that allotment percentage I believe is obtained by dividing the per capita income of the State into the per capita income for the Nation as a whole.

Is the State and Territorial Health Officers Association generally satisfied with that formula?

Dr. BERGSMA. Yes, sir; the executive committee considered that formula and decided to make no further comment about it.

The CHAIRMAN. I had some telegrams from some doctors a few days ago rather sharply critical of that formula. I have not identified the doctors. The telegrams are still on my desk, but the substance of their telegrams is something like this:

They say it seems the height of absurdity to apply a cold, dead formula like the Hill-Burton Hospital Construction Act, when we are dealing with children, and urged strongly against the adoption of that type of formula.

Now, I have not analyzed it myself yet to see what is the basis of their objection, but I am wondering if you were entirely satisfied as a State health officer with the formula for the allocation of funds set forth in the bill?

Dr. BERGSMA. Yes, sir. In the case of our State, we would, of course, get a lesser fraction as contrasted with some other States. But I recognize the relative problem, the relative need, and I presume that those who designed this particular approach were recognizing that relative need and were trying to find a legal way of expressing it.

We had no further objection to it as an executive committee of the State and Territorial Health Officers Association.

The CHAIRMAN. Thank you, Doctor.

Mr. SPRINGER. Doctor, are you the health officer for the State of New Jersey?

Dr. BERGSMA. Yes, sir.

Mr. SPRINGER. Did I understand you to say that in the State of New Jersey the State supplies poliomyelitis vaccine free?

Dr. BERGSMA. No, sir; not at this moment. We have never provided it free because we were never able to purchase it. We do provide other vaccines and have done so for a number of years.

Mr. SPRINGER. Would you name the vaccines you do supply?

Dr. BERGSMA. Such as typhoid and the paratyphoid, pertussis, for diphtheria, for tetanus.

Mr. SPRINGER. Now, I have this question. You heard Mr. Bennett of Florida testify a moment ago?

Dr. BERGSMA. Yes.

Mr. SPRINGER. Do you believe that the amendment which Mr. Bennett proposed there for the State of Florida is one that should apply to the State of New Jersey?

Dr. BERGSMA. Well, sir, I didn't have a copy of his proposed amendment and I didn't study it in any way, but I did get the impression that what he hoped for was that a bill passed at the Federal level would provide not only for the purchase of some vaccine, but also to provide some funds for the administration of the program within the several States.

I can say in regard to that concept that it certainly would be desirable that some reasonable percentage of the total allotment to a State would be usable for administrative purposes, if necessary.

Mr. SPRINGER. Now, in addition, he proposed, and Mr. Chairman, correct me if I make a mistake, he proposed that if there were Federal funds allotted and the State of Florida purchased the vaccine or a proportionate part that they should be allowed to not only use it for administrative purposes, but to use it on any other vaccine program. Am I correct in that?

The CHAIRMAN. I understood that he specifically limited it to the polio vaccine, that he thought they should not be allowed to allocate to some other program.

Mr. SPRINGER. Then I stand corrected.

On just this program alone?

Dr. BERGSMA. Yes.

Mr. SPRINGER. Do you think that is a fair amendment?

Dr. BERGSMA. I think it would be very desirable. The percentage needed in the several States for administrative purposes would vary. The amount that the State might be able to provide within its own existing appropriation would vary and, therefore, I would suggest, sir, if I may, that whatever the Congress considers a reasonable amount percentagewise be allocated as a ceiling, that that much could be used for administrative purposes, if needed, and if not needed that it could be used for more vaccine.

Mr. SPRINGER. First of all, in any amendment, Doctor, I take it you would propose that this money allocated by the Federal Government would be used first for the purchase of vaccine?

Dr. BERGSMA. Yes.

Mr. SPRINGER. And then if there are any funds left, to be used for administration?

Dr. BERGSMA. What other funds would you mean by that?

Mr. SPRINGER. Any portion of the funds which are appropriated and given to you by the Federal Government. That is the other part of the same fund, that is what I mean, which was not used for the purchase of vaccine.

Dr. BERGSMA. I am afraid that I am not clear. I would like to ask, did you mean that a State health officer might receive through this legislation either the vaccine or funds with which to purchase the vaccine and that for the cost of administering this program, the polio

vaccination program, that he would be given the general authorization to use other moneys such as out of the general health account?

Mr. SPRINGER. No. We will start over again. Maybe I can straighten it out.

Would you recommend that the moneys allotted to the State of New Jersey, or the State of Florida, if it is a million dollars, be first used in the purchase of vaccine, in whatever amount is needed?

That is No. 1. That is first priority.

Would you say that should be the first priority?

Dr. BERGSMA. I can foresee quite a few difficulties in that approach. May I suggest an alternate for consideration, that regardless of the amount that a State may be found eligible to receive under the total amount and formula, that a certain percentage of that State allotment be authorized for expenditure for the administration of the program, if necessary, and the balance, which would be an absolute ceiling—let us assume 5 percent were authorized, or 10 percent—then the balance would be usable only for the purchase of vaccine, and the 5 or the 10 or the 7, which you may elect to grant permission for in terms of cost of administration, would represent a ceiling which he could not bypass for administrative cost.

I think that would work better.

Mr. SPRINGER. This bill provides that:

> The Secretary shall approve the application in any State for payments under this Act if such application—

and sets out (a).

On page 4 is (b):

> provides for administration or supervision of administration of the program, included in the application by a single State agency.

Dr. BERGSMA. I interpreted that to mean the cost of administration or supervision at the Federal level as compared to the State level.

Mr. SPRINGER. Is that correct, Mr. Chairman?

The CHAIRMAN. What section is that?

Mr. SPRINGER. Page 4, subsection (b), section 4.

The CHAIRMAN. It is my understanding that the application of a State must provide for the administration by a single State agency.

Does that answer the question?

Mr. SPRINGER. That pursuant or prior to approval by the Secretary of application, the State must submit that application setting forth a program and a plan providing for administration of the plan?

Dr. BERGSMA. That is correct, and the (d) item, as I understood it, related to the cost at the Federal level and not at the State level.

That was my interpretation.

Mr. SPRINGER. I understood as the chairman did, that before they could even get a grant from the Secretary they must set up a means of administering the supervision or administration of the program included in the application by a single State agency.

Now, the point I am in doubt of is whether administration or supervision and administration means administering of the vaccine.

Mr. Chairman, are you clear on that?

The CHAIRMAN. It is my understanding that it means the administration of the entire program.

Mr. SPRINGER. Would that include the inoculation?

The CHAIRMAN. Yes; that is my understanding of the meaning.

Mr. SPRINGER. That is what I understood.

The CHAIRMAN. I may not be quite clear on that point, myself.

Mr. ROBERTS. On that section on page 5, I have not studied the bill very carefully, but it seems to me that is pretty definite that funds appropriated can only be used for the purpose of vaccine. Am I right on that? It said:

> Funds paid to a State under this Act may be used solely for the purpose prior to December 31, 1956——

The CHAIRMAN. I think I am wrong in my interpretation there in rereading the language.

Mr. ROBERTS. The way the bill is written that is all the money can be used for, all the Federal money can be used for is for the purpose of vaccine.

Dr. BERGSMA. That is right.

The CHAIRMAN. Unless an amendment of 5 or 10 percent ceiling such as Mr. Bennett or Dr. Bergsma suggested was adopted.

Mr. ROBERTS. Doctor, do you forsee that in these times of mass vaccinations that there would be a heavier burden on your State agencies right at that particular time than there would be after you get through with one of these mass programs which would call for additional technicians or additional nurses and perhaps additional doctors?

Dr. BERGSMA. It very well could, sir, and in certain States that relative problem would be much greater than in others.

Mr. ROBERTS. Particularly in those States where your ratio of doctors to every thousand persons is smaller than it is in other sections of the country?

Dr. BERGSMA. Yes, and I would judge the problem would also be greater where there were large numbers in the lower economic group.

Mr. ROBERTS. That is all I have.

The CHAIRMAN. Doctor, may I ask this question for some clarification in my own mind:

Do you think that it might be advisable in this legislation to so draft it that each State could choose whatever program it wanted; that is, whether it wanted a limited program or whether it wanted a mass vaccination program such as the foundation proposes to carry out?

Do you think there should be, in other words, more freedom of choice on the part of the States as to what type of program they want than this bill calls for?

Dr. BERGSMA. I think increased flexibility would permit the achieving of the desired end result with less amount of confusion because the needs in the several States do vary greatly and in some situations one could not foretell exactly what the need would be.

A plan to deal with this might be arranged and then for some reason it didn't work as well or as quickly as it was thought desirable and adjustments should then be made to achieve the desired end result and that might not be possible if no flexibility is allowed.

The CHAIRMAN. Is it not true that in other fields of vaccination the programs vary greatly from State to State?

Dr. BERGSMA. Yes, sir.

The CHAIRMAN. That has been one question that I have been a little concerned about in this legislation, the rigidity, more or less, of the program.

I am just wondering if some more flexibility might not be desirable as we consider the bill further. This program, it seems to me, differs largely in two respects from the regular programs that are in effect now:

One, the number of children who should be reached with 2 shots, let us say, in the next 6-month period, and also in the cost of the vaccine as compared to the cost of other vaccines.

Do you agree that those are two points in which it differs largely from the regular vaccination programs that are carried on year after year?

Dr. BERGSMA. Especially on the first count.

The CHAIRMAN. On the first count particularly. We do not know yet how soon the vaccinations will have to be repeated, according to the testimony of our panel.

Dr. BERGSMA. What I meant, sir, was the first item you mentioned was the more important of the two; namely, the tremendous numbers of children who should be reached in a theoretically fairly short period of time.

The CHAIRMAN. That is my understanding. I believe you have previously testified that you believe now under present circumstances that it is advisable and in the public interest to encourage the vaccination of as many children as possible in the shortest time possible?

Dr. BERGSMA. Yes, sir; I do.

The CHAIRMAN. That was my understanding of your statement here in the panel discussion today.

Are there any other questions?

Mr. HAYWORTH. May I ask whether or not the Department indicated a reason for raising the amount from 28 to 35 million?

The CHAIRMAN. In this substance is the justification:

> The total Federal appropriations required for this purpose and for the vaccination of expectant mothers would not exceed $35 million. One of our suggested amendments, you will note will raise the appropriation ceiling from $28 million to $35 million.
>
> The purpose of this change is to allow an ample margin of authorization to cover all sums that might possibly be required in the application of the statutory formula.

I think it largely was a refiguring of the possible number perhaps that will be eligible for free vaccine, plus the other priority groups of pregnant women, and so forth, that did cause the estimate to be raised.

I have a fuller explanation back on my desk, I believe, but this is taken from a statement made before the Senate committee which touched on that one paragraph.

Mr. HAYWORTH. At the cost of $2.33 per set of 3 shots, if we figure the vaccination of only one-fifth of the child population, it would not be necessary to have even $28 million unless something else other than vaccine entered into it. There are fewer than 50 million children.

The CHAIRMAN. We may have to get our slide rules out and do some more figuring on that.

I do not have all of the figures immediately at hand.

At best all I can remember is that formula.

Are there any further questions?

Do you have any further comment, Doctor?

Dr. BERGSMA. No, sir.

The CHAIRMAN. We certainly appreciate your remaining over for these words with us on this subject. I want to thank you and wish you well.

Dr. BERGSMA. Thank you, sir.

The CHAIRMAN. The committee stands adjourned.

(The following material was submitted for the record:)

AMERICAN DRUG MANUFACTURERS ASSOCIATION,
Washington 5, D. C., June 29, 1955.

Hon. J. PERCY PRIEST,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representaties, Washington 25, D. C.

DEAR CONGRESSMAN PRIEST: On behalf of the American Drug Manufacturers Association I would like to thank you for this opportunity to submit a letter on the various bills authorizing Federal funds to provide Salk poliomyelitis vaccine for inoculation of children throughout the United States. The American Drug Manufacturers Association represents makers of prescription medicines; the six producers of the Salk vaccine are members.

We understand that the Committee on Interstate and Foreign Commerce is giving consideration at this time to H. R. 6286 and similar bills. It should be recognized that primary responsibility for the care of the indigent rests in State and local governments. However, if it is deemed necessary to provide Federal money for purchase of limited quantities of Salk polio vaccine for those unable to pay for it themselves, the association would not oppose legislation authorizing such funds, provided that the disbursements follow customary United States Public Health Service channels, procedures, and policies. Individual member companies may differ with the principle of using Federal funds in this field, but this statement represents the association concensus, and has been approved by our executive committee.

The problem of providing ample supplies of safe and efficacious poliomyelitis vaccine is primarily a scientific and medical one. This was clearly demonstrated at your committee hearings with the panel of scientists last week. The decision on whether or not to inoculate a child, and when to perform the inoculation, is a medical decision, which should be made by the parents and the family physician, following a medical examination of the child. Any congressional action which tends to encourage hasty decisions on these points, or which places undue emphasis upon immediate inoculations for all children with the Salk vaccine in its present stage of development, carries with it a grave medical responsibility. This disadvantage would certainly apply to legislation which would provide Federal funds for purchase of sufficient polio vaccine to inoculate all children, regardless of ability to pay; the Association would not favor such measures.

Of course, legislation authorizing the governmental purchase of all, or a substantial portion of Salk vaccine production, would have the further disadvantage of being a step in the direction of socialized medicine, which is generally opposed.

The assocation believes that when increased supplies of the Salk polio vaccine become available, they can be distributed most expeditiously and equitably by following the voluntary allocation program developed by the Department of Health, Education, and Welfare. With the coopertion of the Federal and State Government, the physicians, and the pharmacists, the producing firms can see that the vaccine is distributed to those who need it, and without the imposition of hampering mandatory controls. Voluntary cooperation has always worked better than mandatory action where public-spirited United States citizens are involved.

Although I realize that mandatory controls over distribution and medical use of the Salk vaccine are not involved in H. R. 6286, I thought it advisable to mention at this point the disadvantages of controls additional to those already provided in the Federal Food, Drug, and Cosmetic Act, and the Biologics Control Act.

This letter is submitted for the record, and may be used by you in any way you wish.

Respectfully yours,

KARL BAMBACH,
Executive Vice President.

AMERICAN MEDICAL ASSOCIATION,
Chicago 10, Ill., June 28, 1955.

Hon. J. PERCY PRIEST,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington 25, D. C.

DEAR MR. CHAIRMAN: I should like to take this opportunity on behalf of the American Medical Association to respectfully submit for your consideration our views on H. R. 6286 and H. R. 6287, 84th Congress, now pending before your committee. As we understand these identical measures, they would authorize the appropriation of funds for the purchase and distribution of poliomyelitis vaccine.

The bills would authorize an appropriation of $28 million to assist the States in establishing a grant-in-aid program for the immunization against poliomyelitis of children whose parents are unable to pay. Allotments to States would be determined on the basis of the relative population under age 20 and the per capita income of the States.

In outlining our position on these two bills I refer to the action taken on June 9, 1955, by our house of delegates at our annual meeting in Atlantic City, N. J. Three resolutions were presented to the house of delegates and approved relative to the Salk polio vaccine. The first commended Dr. Salk and expressed the gratitude of the entire medical profession for his monumental contribution to medical science. The second resolution reaffirmed "confidence in the established methods of announcing new and possible beneficial methods in the treatment and prevention of disease" and also reaffirmed "the need for the presentation of reports on medical research before established scientific groups, allowing free discussion and criticism, and the publication of such reports, including methods employed and data acquired on which the results and conclusion are based, in recognized scientific publications." The last of the three resolutions which is particularly germane to the bills under consideration included the following policy statements:

"*Resolved*, That the American Medical Association go on record as disapproving the purchase and distribution of the Salk polio vaccine by any agency of the Federal Government except for those unable to procure it for themselves and that such necessary Federal funds therefor be allocated to the various proper State agencies for such purposes; and be it further

"*Resolved*, That the American Medical Association urge the Congress of the United States to allow the Salk polio vaccine to be produced, distributed and administered in accordance with past procedures on any new drug or vaccine."

I believe it is clear from this resolution that we are not opposed to H. R. 6286 and H. R. 6287, 84th Congress, but that we do not look with favor upon proposals to inject the Federal Government into the immunization program beyond its presently established responsibilities.

In our opinion existing laws are adequate to control the safety and potency of the vaccine. Existing voluntary agreements are adequate to insure its distribution as rapidly as it can be produced to those groups whose need is greater.

Dr. Walter B. Martin, immediate past president of the American Medical Association, has assured the President that the Nation's physicians will cooperate in limiting polio vaccinations to children from 5 through 9 until the vaccine is available in larger supply. The American Medical Association has requested all physicians to administer the vaccine only to children in this age group until further notice. This will assure that the vaccine will be made available first to those most susceptible to the disease.

Physicians have been asked to maintain records on each child vaccinated, showing the name and age of the patient, the date and site of the vaccination, and the manufacturer and lot number of the vaccine used. This voluntary priority vaccination plan follows the recommendation of the National Advisory Committee on Poliomyelitis Vaccine approved by the Secretary of Health, Education, and Welfare and contained in her report to the President on May 16.

I assure you on behalf of the American Medical Association and on behalf of the physicians of the United States that this plan will be followed voluntarily. In accordance with the great traditions of medicine no child will be denied a vaccination because of inability to pay a physician's fee.

For many years we have counseled with individuals and with various agencies of the Government relative to public-health matters. We have promoted State and local health services and have consistently advocated greater responsibility and discretion at the local level in planning for and solving public-health prob-

lems. Our faith in the ability of the medical profession and State and local public-health officers to solve the problems arising from the public demand for poliomyelitis immunizations has been justified, in our opinion by their response to date.

Programs for the administration of the vaccine to children in the most susceptible age groups have already been formulated in many States. In some cases the necessary funds have been appropriated by State legislatures. It is our belief that unless the Federal Government imposes additional requirements, or in some other way hinders the activities of these State and local programs, they will move smoothly as soon as the required vaccine is available.

We feel that the role of the Federal Government in immunization programs is adequately set out in existing law. It is being performed smoothly in the administration of rabies and diphtheria vaccine by State and local health departments. It will continue to function smoothly in the administration of poliomyelitis vaccine. Additional funds may be required but not an additional mechanism.

It is therefore our recommendation that if it is the belief of the committee that some additional legislation is required at this time that it be limited to the type of program outlined in H. R. 6286 or H. R. 6287, 84th Congress. We are convinced that more ambitious proposals which have been advanced are completely unnecessary and will, if enacted, result in an unreasonable expenditure of Federal funds and the possible impairment of State, local, and voluntary programs which are already established or which are now being formulated.

Sincerely yours,

GEORGE F. LULL, M. D.,
Secretary and General Manager.

AMENDMENTS TO S. 1984 AND H. R. 6286 PROPOSED BY DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Omit the part in black brackets, and add the part in italic]

A BILL To provide grants to [assist] States [in assuring that no child is deprived of an opportunity for immunization against poliomyelitis because of inability to pay the costs of vaccination] for the purchase of poliomyelitis vaccine, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Poliomyelitis [Immunization] *Vaccination* Assistance Act of 1955."

AUTHORIZATION OF APPROPRIATIONS

SEC. 2. For the purpose of assisting States to assure that [no child will be denied immunization against poliomyelitis], during the current shortage of the poliomyelitis vaccine, [because of inability to pay the cost thereof,] *every child has an opportunity to be vaccinated against poliomyelitis*, there is hereby authorized to be appropriated not to exceed [$28,000,000,] *$35,000,000*, to remain available until December 31, 1956. Sums appropriated pursuant to this section shall be used for making payments to States which have submitted, and had approved by the Secretary of Health, Education, and Welfare, applications for carrying out the purposes of this Act.

ALLOTMENTS TO STATES

SEC. 3. (a) From the sums appropriated pursuant to section 2, the Secretary shall allot to each State which has an application approved pursuant to section 4 an amount equal to 20 per centum of the number of [unimmunized] *unvaccinated* children in such State multiplied by the product of (1) the cost of the poliomyelitis vaccine per child and (2) the State's allotment percentage. The amount so computed for each State shall be reduced by the percentage by which such sums appropriated pursuant to section 2 are less than the total of the amounts so computed for all States.

(b) A State's allotment percentage shall be equal to the per capita income of the United States divided by the per capita income of the State. Such percentage shall be determined by the Secretary[, in accordance with regulations,] on the basis of information furnished by the Department of Commerce; except that the allotment percentage for Hawaii shall be 100 per centum and for Alaska, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Canal Zone shall be equal to the allotment percentage determined above for the one of the forty-eight States which has the lowest per capita income.

STATE APPLICATIONS FOR FUNDS

SEC. 4. The Secretary shall approve the application of any State for payments under this Act if such application—

(a) [sets forth a statewide program for use of the] *provides that all* poloimeylitis vaccine purchased with funds paid to the State under this Act [, which contains] *shall be used pursuant to a statewide plan for vaccinations (through public agencies, private physicians, or otherwise) which provides* reasonable assurance that [no child, of if (and for so long as)] every child in the State (or, if any priority groups are established by the Secretary under this Act, [no child] *every such child* within such priority group [or groups, will be denied vaccination] or groups) *will have an opportunity to be vaccinated* against poliomyelitis [because of inability to pay the cost thereof] : *Provided*, That [this shall not prevent a State from providing for the free vaccination against poliomyelitis, without regard to ability to pay, of all unimmunized children, or all such children within any one or more groups determined by the State, but, in such case,], *if the statewide plan is limited to such priority group or groups*, the amount paid to such State under this Act [with respect to the poliomyelitis vaccine for such children] may not exceed the allotment percentage for such State multiplied by the cost of [the] *poliomyelitis* vaccine for 20 per centum of [such children :] *the unvaccinated children in such group or groups;*

(b) provides for administration or supervision of administration of the [program] *plan* included in the application by a single State agency;

(c) provides that the State agency will make such reports, in such form and containing such information, as the Secretary may from time to time reasonably require to carry out his functions under this Act, and comply with such provisions as he may from time to time find necessary to assure the correctness and verification of such reports; and

(d) provides such accounting, budgeting, and other fiscal methods and procedures as are necessary for the proper and efficient administration of the [program.] *Plan.*

PAYMENTS TO STATES

SEC. 5. The Secretary shall from time to time estimate the amount to be paid to each State under the provisions of this Act for any period, and shall pay such amount to such State, from the allotment available therefor, reduced or increased, as the case may be, by any sum (not previously adjusted under this section) by which he finds that his estimate of the amount to be paid to the State for any prior period under this Act was greater or less than the amount which should have been paid to the State for such prior period under this Act. Such payments shall be made in such installments as the Secretary may determine.

USE OF FUNDS PAID TO STATES

SEC. 6. Funds paid to a State under this Act may be used solely for the purchase, prior to December 31, 1956, of the poliomyelitis vaccine for use in carrying out the [program] *plan* set forth in the application of such State approved pursuant to section 4.

FURNISHING OF VACCINE BY SECRETARY

SEC. 7. At the request of any State the Secretary may use all or any portion of the allotment of such State under this Act for the purchase of the poliomyelitis vaccine, to be furnished to the State in lieu of such State's allotment (or such portion thereof). Vaccine so furnished shall be subject to the same requirements as to use as vaccine purchased from payments to States pursuant to this Act.

PRIORITIES AND ADVISORY COMMITTEE

SEC. 8. Priorities established by the Secretary for purposes of section 4 (a) shall be based on the relative susceptibility of various [age] groups of children to poliomyelitis. The Secretary is authorized to establish an advisory committee [on distribution of the poliomyelitis vaccine] to advise and assist him in the establishment of such priorities. Appointed members of such committee who are not otherwise in the employ of the United States, while attending con-

ferences or meetings of the committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at a rate to be fixed by the Secretary but not exceeding $50 per diem, including travel time, and while away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law (5 U. S. C. 73b–2).

DIVERSION OF FEDERAL FUNDS

SEC. 9. Whenever the Secretary, after reasonbale notice and opportunity for hearing to the State agency administering or supervising the administration of the [program] *plan* included in the application of such State approved under section 4, finds that—

(a) such State agency is not complying substantially with the provisions of this Act or the terms and conditions of its approved application; or

(b) any funds paid to such State or supplies of vaccine furnished to it under this Act have been diverted from the purposes for which paid or furnished;

the Secretary shall notify such State agency that no further payments will be made (or no further supplies of vaccine will be furnished) to the State under this Act until he is satisfied that there is no longer any failure to comply or the diversion has been corrected or, if compliance or correction is impossible, until such State agency repays or arranges for the repayment of Federal funds which have been diverted or improperly expended (or for repayment of the cost of the vaccine which has been diverted).

DEFINITIONS

SEC. 10. For purposes of this Act—

(a) The term "Secretary" means the Secretary of Health, Education, and Welfare;

(b) (1) The term "child" means any individual who has not attained the age of twenty years; and any expectant mother;

(2) The number of children shall be determined by the Secretary, as of June 30, 1955, on the basis of *estimates developed after consideration of* the latest information furnished by the Department of Commerce *or any other department or agency of the United States;*

(3) The number of [unimmunized] *unvaccinated* children means the number of [such] children, reduced by [the extent to which any such child has received the vaccinations against poliomyelitis, determined by the Secretary as of such date or dates as he may select for purposes of this Act;] (A) *the number who were vaccinated against poliomyelitis during 1954, and (B) two-thirds of the number who the Secretary estimates will receive vaccination under the current program of the National Foundation for Infantile Paralysis;*

(c) The term "State" includes Alaska, Hawaii, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Canal Zone, and the District of Columbia;

(d) The cost of the poliomyelitis vaccine shall be determined by the Secretary on the basis of information available to him; and such cost may be determined from time to time or as of a specified date and may be determined to be a single figure for all States or varied in accordance with actual cost.

EXPLANATION OF HEW AMENDMENTS TO S. 1984 AND H. R. 6286

1. Nature and scope of State vaccination programs to be assisted with Federal grants (p. 1, lines 1–4; p. 2, lines 10–15; p. 2, lines 23–26; p. 3, lines 1–17): The amendments proposed to be made in the title of the bill, section 2, and section 4 are all designed to make it absolutely clear first that the bill is not intended to either require or encourage States to set up poliomyelitis vaccination programs limited to children unable to pay the cost of vaccinations, and second that States, in order to participate in the Federal assistance made available by the bill, must have a statewide vaccination plan which indicates how all children—not just those who are unable to pay for their own vaccinations—are expected to secure vaccinations against poliomyelitis. These amendments would require that there be a statewide vaccination plan which provides reasonable assurance that all children (or all children in priority groups) will have an opportunity to be vaccinated—either by their own physicians at their own expense, or through public health clinics at public expense, or otherwise.

2. Increase in appropriation ceiling (p. 1, line 16): With a view toward assuring that the appropriation authorization will be ample notwithstanding unforeseen contingencies (such as an increase in the cost of the vaccine) to provide all sums called for by the allotment formula in section 3 of the bill, this amendment would increase the appropriation authorization from $28 million to $35 million.

3. Change from "immunization" to "vaccination": These amendments, throughout the bill, are proposed because from a medical standpoint the term "vaccinated" or "unvaccinated" is preferable. Many children have been immunized by natural occurrence of the disease and some are not immunized after one or more injections of the vaccine.

4. Broadening of Secretary's authority to establish "priorities" (p. 5, line 4): This amendment will give more flexibility to the priority system by permitting of possible deviations from the straight "age group" basis in case epidemiological factors (not now clearly foreseeable) might warrant some different priority basis.

5. Inclusion of expectant mothers (p. 6, line 13): This amendment changes the definition of "child" so as to include expectant mothers for all purposes of the bill.

6. Amendments to statistical bases for counting child population and number of unvaccinated children (p. 6, lines 16–26): These amendments would permit use of estimates from sources other than the Department of Commerce, as to the number of children in various age groups, and would clearly tie the term "unvaccinated children" to those not vaccinated under the program of the National Foundation for Infantile Paralysis.

7. Miscellaneous amendments (p. 2, line 14; p. 5, lines 5–6): These are purely technical drafting amendments.

STATEMENT BY OVETA CULP HOBBY, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, IN SUPPORT OF S. 1984 (COMPANION BILL TO H. R. 6286)

Mr. Chairman and members of the committee, I appreciate the opportunity of appearing before your committee this morning to indicate the views of our Department on S. 1984 and S. 2147, bills authorizing Federal grants to the States for the purchase of poliomyelitis vaccine.

Federal grants to States to assist in the purchase of vaccine are one of the key recommendations in our May 16 report to the President on distribution of the Salk vaccine. This report, you will recall, sets forth a program which:

1. Will apply to the distribution of vaccine after the vaccine requirements of the NFIP program have been met for the country as a whole.
2. Assures equitable distribution of available vaccine among the States and Territories.
3. Gives first priority to children in the age categories most in need of protection.
4. Places responsibility for establishing national priority and interstate allocation policies in the Department of Health, Education, and Welfare.
5. Places responsibility for intrastate distribution policies in a single State agency designated by the governor for this purpose.
6. Provides for joint Federal-State action in assuring that the cost of vaccination will not be a barrier to its equitable distribution to children in the priority age groups.

ANALYSIS OF BILLS

It is this last point—Federal-State action to assure an opportunity for vaccination to all children—that is the common objective of the two bills presently under consideration by your committee. Both bills authorize Federal grants to the States for the purchase of vaccine. Both place responsibility on the States for developing and administering State plans for the distribution and use of vaccine so purchased. They also have identical or similar provisions relating to administration of State plans, procedures for payments to States, grants of vaccine in lieu of cash grants on request of any State, and the establishment of an expert committee to advise the Secretary on the designation of priority groups. They differ, however, as to the basis on which Federal aid is to be provided and as to the State plan conditions governing eligibility for Federal assistance. Before analyzing and evaluating these essential differences, let me briefly summarize the key provisions of the two bills.

Summary of S. 1984

I should like to explain at this point, Mr. Chairman, that we have prepared several amendments to S. 1984, mostly of a technical or clarifying nature, which

we believe will improve the bill as introduced. Copies of the bill incorporating these amendments have been prepared for the use of your committee, and the following comments on the provisions of S. 1984 are based upon this draft revision.

S. 1984 would authorize grants to assist the States in the purchase of vaccine. On request of any State, the Secretary could furnish vaccine in lieu of a cash grant. To be eligible for a grant, a State would submit an application for approval by the Secretary. This application must include a statewide plan for vaccinations which provides reasonable assurance that all children—including those unable to pay the costs of vaccination—will have an opportunity to be vaccinated. The means of implementing this assurance would be left to the discretion of the States.

I should like to point out here, Mr. Chairman, that our amendments include changes in the language of the bill relating to the scope of the State plan and to the assurances by the States as to the opportunity for all children to be vaccinated. These changes are designed to make it clear that the bill will not require or encourage States to establish a separate vaccination program for children from low-income families or to employ any "means test" to determine eligibility for free vaccination programs.

In administering this program, the Secretary would be authorized to establish priority groups within the total child population. The States' assurances regarding the opportunity to be vaccinated would have to apply only to the priority groups so established—until sufficient vaccine becomes available to permit enlarging the priority groups or eliminating them altogether. As you know, we have already established the 5 to 9 age group as the first priority, upon recommendation of the National Advisory Committee on Poliomyelitis Vaccine. Succeeding priority groups will be established in due course.

The total amount of Federal grant funds, and the allocation of these funds among the several States, would be determined by a statutory formula. This formula would take into account the number of unvaccinated children in each State, the relative per capita incomes of the several States, and the cost of the vaccine. For the Nation as a whole, the Federal funds authorized would be sufficient to purchase vaccine to provide complete vaccination for about 22 percent of the children who have not previously been vaccinated under the program sponsored by the National Foundation for Infantile Paralysis. This would be approximately 13,350,000 children.

The total Federal appropriations required for this purpose, and for the vaccination of expectant mothers, would not exceed $35 million. One of our suggested amendments, you will note, would raise the appropriation ceiling from $28 million to $35 million. The purpose of this change is to allow an ample margin of authorization to cover all sums that might possibly be required in the application of the statutory formula.

The formula would provide relatively more Federal aid for the lower income States. Thus the allotment for the lowest income State would be sufficient to purchase vaccine for 41 percent of the unvaccinated children, while the allotment for the highest income State would cover vaccine costs for approximately 15 percent of such children.

The grants authorized under S. 1984 are limited to the purchase of vaccine. We are also preparing a supplemental appropriation request—based on existing grant authority in the Public Health Service Act—to help the States meet their costs relating to the development and administration of programs for the intrastate distribution and use of poliomyelitis vaccine.

The appropriations required for this purpose would not be great. We believe, however, that an additional appropriation for this purpose would be helpful in assuring prompt and effective State action. With many State legislatures not in session, current and prospective poliomyelitis programs have placed a strain on the administrative budgets of many State health departments. It would be shortsighted, indeed, to permit this obstacle to impede the progress of Federal-State programs for distribution and use of the vaccine.

Summary of S. 2147

S. 2147 contains neither a specific appropriations ceiling nor an allotment formula. Rather, it provides that the Secretary shall pay to each State an amount equal to the cost of all vaccine used in carrying out the program set forth in an application which has been approved by the Secretary. If all States took maximum advantage of the Federal aid authorized, we estimate that the total appropriations required would approximate $130 million.

To be eligible for approval, a State application must set forth a program or programs affording opportunity for free vaccinations to (1) all children in one or more age groups throughout the State or in one or more areas of the State or (2) all persons in any priority groups specified by the Secretary. Thus a State could not in any way limit the availability of free vaccinations among persons in the priority groups covered by the plan. Federal aid would be confined to those areas or groups within a State covered by such free vaccination programs.

In other words, as we understand the intent of the bill, it is designed to encourage States to offer completely free vaccinations (presumably through programs organized on a communitywide basis) to all persons in priority groups within the States. The Federal Government would undertake to pay the costs of all vaccine required for such free vaccinations. In addition, the bill would require the Federal Government to pay the costs of vaccine for persons in such groups and areas who may elect to go to their private physicians and pay for the professional costs of administering the vaccine.

Principal differences

There are two principal differences between the approaches and provisions of these bills:

1. The grants authorized by S. 1984 are designed to supplement State, local, and private funds available for the purchase of vaccine for children in the priority groups. S. 2147 would authorize payment by the Federal Government of the entire cost of purchasing such vaccine. S. 1984 would authorize not to exceed $35 million in Federal appropriations for this purpose. The appropriations requirements of S. 2147 are difficult to forecast, but they could be as much as $130 million, or about $95 million greater than those of S. 1984.

2. S. 2147 would restrict Federal aid to those areas or groups covered by communitywide free vaccination programs. For such areas and groups the Federal Government would pay for all the vaccine used. Other areas or groups would receive no Federal assistance under the bill. S. 1984, on the other hand, would provide aid on a statewide basis, on assurance that all children in the State would be provided a reasonable opportunity to be vaccinated. The States and communities would be free to determine the scope and conditions of free vaccination programs.

EVALUATION OF ALTERNATIVE APPROACHES

We are firmly convinced, Mr. Chairman, that the supplementary Federal aid authorized by S. 1984 will achieve the desired objective and that the 100 percent Federal absorption of vaccine costs provided for in S. 2147 is unnecessary. It is not required either for reasons of financial need or as a means of avoiding discriminatory policies or practices.

By any standard of ability to pay that may be employed, most families could afford the cost of vaccination for their children. On the basis of preliminary price quotations, the cost of the vaccine itself— when obtained through a private physician—will probably range from $3.50 to $4.20. Although there will be some variations in physicians' fees, inoculations are customarily provided at the prevailing rates for office calls. Thus, the total cost per child will not be great.

Even though most families can afford the cost of vaccinating their children, we must be sure that such protection can also be offered to children from low-income families and from large families where the combined cost might be an obstacle to vaccination. We should recognize, however, that the provision of such inoculations is a responsibility that has been generally accepted by the States and communities, with the cooperation of the medical profession. Free immunizations for various communicable diseases—such as diphtheria and smallpox—are an accepted feature of public health programs in all parts of the country.

The methods and procedures for encouraging and providing these services differ from community to community. In some areas the public-health agency works through the schools and parent-teacher organizations—both to encourage inoculations through family physicians and to make known the availability of free injections at public health centers or in connection with preschool health clinics. In other communities the public health agency provides free vaccine for the use of private physicians, who in turn provide free inoculations for those who cannot afford to pay.

These services are well established and accepted in nearly all communities, and they are provided in a manner which is not discriminatory or offensive. Seldom, if ever, is any formal means test applied. Rather, free inoculations are avail-

able at clinics or other centers to all who request them, but the great majority of those who are able to pay prefer to go to their family physicians for preventive services as well as for treatment. The arrangement is analogous to the availability of pediatric services from a well-baby clinic operated by the local health department. Many mothers—particularly in communities where the income is at least average—prefer to take their children to a private pediatrician or family doctor, but there is certainly no stigma attached to the use of the public clinic.

In our opinion it is both practicable and desirable to permit States and localities to apply these established policies and procedures to their programs for poliomyelitis vaccination. If they wish to adopt special programs for this purpose they should have that privilege, but we see no reason for the Federal Government to require or promote a separate and different local policy for immunization against one particular disease.

That many States and communities are willing and able to provide funds for polio vaccination programs is clearly evident. Steps have already been taken by State legislatures, local governments, voluntary organization, professional societies, and other civic groups to assure the opportunity of vaccination to children in priority groups. Additional plans for financing the costs of vaccination programs are currently in preparation in other States and communities.

We believe, however, that Federal participation in such financing is desirable in order to provide additional assurance that the opportunity for vaccination will be afforded to all children in all parts of the country. We also believe that Federal sharing in the costs of vaccination will serve to accelerate State and community efforts toward this end, and will help offset variations in State and local financial resources. The backlog costs of assuring vaccinations for all children from 1 to 19 in a comparatively brief period of time will put a strain on the financial resources of some low-income States and communities.

Our belief that S. 1984 offers the better approach to our national objective is based not only on these positive advantages, but also on three features or aspects of S. 2147 with which we are not in agreement.

First, it is geared exclusively to communitywide, free vaccination programs. In some communities such programs might be administered on a decentralized basis, with the participation of all private physicians in the area. For the most part, however, a policy of free vaccinations for all will require some form of mass program on a centralized basis. We believe that the Federal grant program should permit the adoption of such mass programs at the discretion of the State or community. We do not believe, however, that mass, free programs are necessarily suited to the needs and preferences of all communities. We therefore believe that this feature of S. 2147 would result in an undesirable degree of rigidity in the program as a whole.

Second, because of this emphasis on communitywide, free vaccination programs, the provisions of S. 2147 would permit discriminations among States and communities which we believe are inequitable and unwise. Thus it would authorize complete Federal payment of vaccine costs for all children in groups or communities covered by programs of free vaccination, but would provide no Federal assistance whatsoever for other groups or communities—even if there were public programs adequate to provide free vaccinations for those who wish or need them. We believe that such an all-or-nothing policy is unnecessary and undesirable in any Federal-State cooperative program.

Third, S. 2147 appears to assume a lack of State, local, and private ability or initiative to take advantage of new public health advances. We believe that this concept is erroneous. The proper perspective, in our view, is that an important new advance in public health has been made available. Our people, our communities, and our States fully recognize this and will step forward to take advantage of the opportunity. The appropriate role of the Federal Government is to provide supplementary funds to States to assure that their established public-health programs can absorb the impact of the sudden and substantial demand created by the introduction of this new vaccine. We do not believe that public health practice with respect to the Salk vaccine need differ substantially from the practice applicable to other vaccines.

In summary, Mr. Chairman, we believe that S. 1984 offers the best approach to a Federal-State program of poliomyelitis vaccination. It will supplement the combined financial resources of individual families, civic groups, and city, county, and State governments. It will reinforce, rather than replace, established public-health policies and programs. It will provide Federal aid to strengthen programs for all groups of children in all communities in the States, but it will leave the choice of program methods and policies in the hands of the

States and communities. **With the assistance provided pursuant to its provisions, we are confident that we can achieve our National goal of making vaccination against poliomyelitis available to all children in the United States.**

Estimated allocations of funds for purchase of poliomyelitis vaccine

State	Estimated number unvaccinated children 0 to 19 years [1] (1)	Percent of children on basis of which Federal payments would be made (2)	Estimated cost of vaccine for unvaccinated children under Federal aid program at $2.33 for 3 cc.'s (3)	Estimated cost of vaccine for 3d shot for col. 2 percentage of children under current NFIP program at 78 cents per cc. (4)	Total estimated allocation of funds to each State (col. 3 plus col. 4) (5)
Total	51,710,003	22.1	$26,636,168	$1,501,508	$28,137,676
Alabama	1,156,606	32.7	881,229	51,588	932,817
Arizona	338,000	23.2	182,709	11,762	194,471
Arkansas	677,986	36.4	575,014	34,323	609,337
California	3,644,663	16.8	1,426,666	73,343	1,500,009
Colorado	439,450	20.4	208,880	15,414	224,294
Connecticut	593,651	15.6	215,781	14,779	230,560
Delaware	105,435	14.8	36,357	2,788	39,145
District of Columbia	244,692	16.2	92,361	3,577	95,938
Florida	1,031,072	25.0	600,599	36,431	637,030
Georgia	1,294,359	28.9	871,583	56,274	927,857
Idaho	217,430	24.2	122,600	7,708	130,308
Illinois	2,671,902	16.4	1,020,987	54,921	1,075,908
Indiana	1,254,362	18.6	543,615	42,987	586,602
Iowa	833,529	22.5	436,978	25,848	462,826
Kansas	616,796	22.0	316,169	19,498	335,667
Kentucky	1,039,714	29.3	709,802	41,572	751,374
Louisiana	1,067,563	27.4	681,553	37,577	719,130
Maine	298,615	25.0	173,944	9,298	183,242
Maryland	801,000	18.4	343,405	20,093	363,498
Massachusetts	1,397,347	18.9	615,351	32,946	648,297
Michigan	2,217,889	17.1	883,673	57,365	941,038
Minnesota	1,045,626	22.1	538,423	25,060	563,483
Mississippi	841,348	41.0	803,740	50,920	854,660
Missouri	1,218,853	20.7	587,866	34,541	622,407
Montana	214,388	20.2	100,903	5,203	106,106
Nebraska	430,299	22.3	223,580	11,681	235,261
Nevada	59,487	15.7	21,760	1,682	23,442
New Hampshire	160,239	21.0	78,404	4,533	82,937
New Jersey	1,427,278	16.3	542,065	32,088	574,153
New Mexico	294,568	25.4	174,331	11,973	186,304
New York	4,114,386	15.8	1,514,670	89,059	1,603,729
North Carolina	1,563,138	31.2	1,136,339	61,137	1,197,476
North Dakota	231,552	26.4	142,433	6,763	149,196
Ohio	2,650,539	17.0	1,049,879	58,416	1,108,295
Oklahoma	738,639	25.6	440,584	23,863	464,447
Oregon	511,201	19.8	235,838	13,061	248,899
Pennsylvania	3,274,718	18.8	1,434,458	70,209	1,504,667
Rhode Island	229,862	19.5	104,438	5,581	110,019
South Carolina	859,907	31.2	625,116	37,223	662,339
South Dakota	234,106	25.1	136,913	6,806	143,719
Tennessee	1,145,717	28.8	768,821	46,419	815,240
Texas	2,787,289	23.1	1,500,203	100,127	1,600,330
Utah	279,328	22.6	147,088	9,140	156,228
Vermont	126,307	24.4	71,808	3,775	75,583
Virginia	1,168,663	25.1	683,468	42,041	725,509
Washington	793,862	18.2	336,645	17,973	354,618
West Virginia	696,270	27.2	441,267	26,536	467,803
Wisconsin	1,151,779	20.0	536,729	28,357	565,086
Wyoming	104,739	20.7	50,517	2,902	53,419
Alaska	48,000	41.0	45,854	3,198	49,052
Hawaii	167,644	20.0	78,123	4,267	82,390
Puerto Rico	1,138,000	41.0	1,087,131	15,990	1,103,121
Virgin Islands	11,000	41.0	10,508	----------	10,508
Canal Zone	13,210	41.0	12,619	892	13,511
Guam	23,000	41.0	21,972	----------	21,972
American Samoa	13,000	41.0	12,419	----------	12,419

[1] Estimated child population as of June 30, 1955, minus children vaccinated in NFIP field trials and the estimated number of children to receive vaccination in the current NFIP program.

[H. R. 7126, 84th Cong., 1st sess.]

A BILL To provide grants to assist States to meet the cost of poliomyelitis vaccination programs, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Poliomyelitis Vaccination Assistance Act of 1955".

AUTHORIZATION OF APPROPRIATIONS

SEC. 2. There is hereby authorized to be appropriated, to remain available until December 31, ~~1956~~ *1957*, such sums as may be necessary for making payments to States which have submitted, and had approved by the Secretary of Health, Education, and Welfare, applications for grants under this Act.

ALLOTMENTS TO STATES

SEC. 3. (a) From the sums appropriated pursuant to section 2, the Secretary shall allot to each State which has an application approved pursuant to section 4—

(1) an amount equal to 25 percentum of the number of unvaccinated eligible persons in such State multiplied by the product of (A) the cost of the poliomyelitis vaccine per eligible person, and (B) the State's allotment percentage; and

(2) an amount sufficient to match on an equal basis the cost of poliomyelitis vaccine purchased with funds of the State, its political subdivisions, and *approved* nonprofit organizations in the State and used in carrying out the application of the State approved pursuant to section 4 of this Act; and

(3) an additional amount equal to 20 percentum of allotments available to the State under paragraphs (1) and (2) of this subsection, such additional amount to be available for expenditure only in accordance with the provisions of section 6 (b) of this Act.

(b) A State's allotment percentage shall be equal to the per capita income of the United States divided by the per capita income of the State. Such percentage shall be determined by the Secretary on the basis of information furnished by the Department of Commerce; except that the allotment percentage for Hawaii shall be 100 percentum and for Alaska, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Canal Zone shall be equal to the allotment percentage determined above for the one of the forty-eight States which has the lowest per capita income.

STATE APPLICATIONS FOR FUNDS

SEC. 4. The Secretary shall approve the application of any State for payments under this Act if such application—

(a) provides that all poliomyelitis vaccine purchased with funds paid to the State under this Act shall be used *for the vaccination of eligible persons* pursuant to a plan which sets forth the method or methods by which vaccinations will be made available throughout the State (through public agencies, *approved nonprofit organizations*, private physicians, or otherwise) and which provides reasonable assurances that all eligible persons in the State (or, if the State determines that vaccinations shall be confined to a certain group or groups of eligible persons throughout the State, all eligible persons in such group or groups) will have an opportunity to be vaccinated against poliomyelitis: *Provided*, That if the plan of the State is limited to such group or groups, the amount paid to such State from that part of its allotment computed in accordance with section 3 (a) (1) of this Act may not exceed the allotment *percentage* of such State multiplied by the cost of poliomyelitis vaccine for 25 per centum of the unvaccinated eligible persons in such group or groups;

(b) provides that in poliomyelitis vaccination programs conducted by public agencies in the State no means test or other discrimination based on financial ability of individuals will be imposed to limit the eligibility of persons to receive vaccination against poliomyelitis;

(c) provides for administration of supervision of administration of the plan included in the application by a single State agency;

(d) provides that the State agency will make such reports, in such form and containing such information, as the Secretary may from time to time reasonably require to carry out his functions under this Act, and comply with such provisions as he may from time to time find necessary to assure the correctness and verification of such reports; and

(e) provides such accounting, budgeting, and other fiscal methods and procedures as are necessary for the proper and efficient administration of the plan.

PAYMENTS TO STATES

SEC. 5. The Secretary shall from time to time estimate the amount to be paid to each State under the provisions of this Act for any period, and shall pay such amount to such State, from the allotment available therefor, reduced or increased, as the case may be, by any sum (not previously adjusted under this section) by which he finds that his estimate of the amount to be paid to the State for any prior period under this Act was greater or less than the amount which should have been paid to the State for such prior period under this Act. Such payments shall be made in such installments as the Secretary may determine.

USE OF FUNDS PAID TO STATES

SEC. 6. (a) Funds paid to a State from that part of its allotment computed in accordance with section 3 (a) (1) and 3 (a) (2) of this Act may be used solely for the purchase, prior to December 31, ~~1956~~ *1957*, of the poliomyelitis vaccine for use in carrying out the plan set forth in the application of such State approved pursuant to section 4.

(b) Funds paid to a State from that part of its allotment computed in accordance with section 3 (a) (3) of this Act may be used prior to December 31, ~~1956~~ *1957*, only for planning poliomyelitis vaccination programs throughout the State and for conducting such programs through public agencies in the State in accordance with the plan set forth in the application of such State approved pursuant to section 4.

(c) Nothing in this Act shall limit funds granted to a State under other provisions of Federal legislation from being available to purchase poliomyelitis vaccine or to plan and conduct poliomyelitis vaccination programs in accordance with approved State plans applicable to such grants.

FURNISHING OF VACCINE BY SECRETARY

SEC. 7. At the request of any State the Secretary may use all or any portion of the allotment of such State under this Act for the purchase, in accordance with State specifications, of the poliomyelitis vaccine, to be furnished to the State in lieu of such State's allotment (or such portion thereof). Vaccine so furnished shall be subject to the same requirements as to use as vaccine purchased from payments to States pursuant to this Act.

DIVERSION OF FEDERAL FUNDS

SEC. 8. Whenever the Secretary, after reasonable notice and opportunity for hearing to the State agency administering or supervising the administration of the plan included in the application of such State approved under section 4, finds that—

(a) such State agency is not complying substantially with the provisions of this Act or the terms and conditions of its approved applications; or

(b) any funds paid to such State or supplies of vaccine furnished to it under this Act have been diverted from the purposes for which paid or furnished;

the Secretary shall notify such State agency that no further payments will be made (or no further supplies of vaccine will be furnished) to the State under this Act until he is satisfied that there is no longer any failure to comply or the diversion has been corrected or, if compliance or correction is impossible, until such State agency repays or arranges for the repayment of Federal funds which have been diverted or improperly expended (or for repayment of the costs of the vaccine which has been diverted).

DEFINITIONS

SEC. 9. For purposes of this Act—

(a) The term "Secretary" means the Secretary of Health, Education, and Welfare.

(b) (1) The term "eligible person" means any individual who has not attained the age of twenty years and any expectant mother.

(2) The number of eligible persons shall be determined by the Secretary, as of June 30, 1955, on the basis of estimates developed after consideration of the latest information furnished by the Department of Commerce or any other department or agency of the United States.

(3) The number of unvaccinated eligible persons means the number of eligible persons, reduced by (A) the number who were vaccinated against poliomyelitis during 1954, and (B) two-thirds of the number who the Secretary estimates will receive vaccination under the current program of the National Foundation for Infantile Paralysis.

(c) The term "State" includes Alaska, Hawaii, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Canal Zone, and the District of Columbia.

(d) The cost of the poliomyelitis vaccine shall be determined by the Secretary on the basis of information available to him; and such cost may be determined from time to time or as of a specified date and may be determined to be a single figure for all States or varied in accordance with actual cost.

(e) The term "approved nonprofit organization" means, in the case of any State, a nonprofit organization approved by the State agency responsible for administration or supervision of administration of the State plan.

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE,
Washington, D. C., July 8, 1955.

Hon. J. PERCY PRIEST,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

DEAR MR. CHAIRMAN: This letter is in response to your request of July 6, 1955, for a report on H. R. 7126, a bill to provide grants to assist States to meet the cost of poliomyelitis vaccination programs, and for other purposes.

In its general objectives, and in many of its key provisions, the bill is similar to H. R. 6286, which, with some amendments subsequently suggested for your committee's consideration, implemented the proposals of the President and this Department for Federal assistance to States in meeting the costs of poliomyelitis vaccination programs. In a number of particulars, however, H. R. 7126 modifies or departs from the provisions of H. R. 6286. The principal differences are:

(1) H. R. 6286 authorizes a formula grant—based on child population, the relative per capita incomes of the several States, and the cost of the vaccine—designed to cover the cost of vaccine for 20 percent of the unvaccinated child poulation in the average-income State. H. R. 7126 authorizes a formula grant based on the same three factors, but designed to provide vaccine for 25 percent of the eligible persons in the average income State.

(2) In addition, H. R. 7126 authorizes open-end Federal grants, on a 50–50 matching basis, for any additional vaccine purchased by the States, local governments, or voluntary organizations. There is no comparable provision in H. R. 6286.

(3) H. R. 7126 authorizes additional grants for the costs of planning and conducting vaccination programs through public agencies in the States—the amount of State allotments for this purpose being equal to 20 percent of the allotments for the purchase of vaccine. While H. R. 6286 contains no provision for State operating expenses, Federal aid has been proposed by this Department in a supplemental appropriation request, based upon existing authority in the Public Health Service Act. These supplemental funds would be available to the States to assist them in carrying out an equitable intrastate system of vaccine distribution. They could also be used by the States for conducting public vaccination programs, although it is contemplated that the States and communities would provide the major portion of these operating expenses.

(4) H. R. 7126 specifically provides that, in vaccination programs conducted by State and local public agencies, "no means test or other discrimination based on financial ability of individuals will be imposed to limit the eligibility of per-

sons to receive vaccination against poliomyelitis." While H. R. 6286 does not require or encourage such limitations on eligibility, it would leave the determination of eligibility to the State and local governments.

(5) H. R. 6286 includes authorizing the Secretary to establish priority groups based on the relative susceptibility of various age groups to poliomyelitis and to establish an advisory committee on distribution of poliomyelitis vaccine. H. R. 7126 contains no comparable provisions.

With respect to the formula grant, it is difficult to determine, on any exact statistical basis, the optimum percentage figure for the Nation as a whole. In our opinion the 20-percent figure, which would provide vaccine for 22 percent of the unvaccinated child population for the Nation as a whole, would be adequate, but we would not object to the 25-percent figure in H. R. 7126.

In our opinion vaccine would be made fully available to the balance of the child population through private purchase or, in those States and communities which wish to adopt more extensive free vaccination programs, through funds from public and voluntary sources. For these reasons, we do not believe the provision of H. R. 7126 authorizing aid over and above the basic grant to each State—on an open-end 50–50 matching basis—is necessary or appropriate. We also have serious reservations regarding the policy of permitting funds from voluntary agencies to be included with State and local funds for the purpose of matching Federal grants.

As indicated above, this Department's proposal grants to States for purposes of planning conducting vaccination programs is included in a supplemental appropriation request based upon existing authority in the Public Health Service Act. We believe that this is the most satisfactory arrangement, since it permits the use of funds from a single Federal grant for the administrative costs of two closely related State activities—(1) the planning and administration of intrastate programs for the equitable distribution of vaccine through public and commercial channels during the period of short supply, and (2) the planning and conduct of State and local public vaccination programs. In our opinion, the only justification for a separate allotment for the second of these two related activities is that it would permit additional Federal aid for operating expenses in States which wish to take advantage of the open-end matching grants authorized by H. R. 7126. We believe that those States or localities which elect to undertake more extensive public vaccination programs can reasonably be expected to asume the additional operating expenses involved.

We believe that the inclusion of provisions relating to the establishment of priority groups and to the appointment of an advisory council, as contained in H. R. 6286, would be desirable in order to indicate the interrelationship between vaccine distribution policies and State and local vaccination programs.

In reviewing the provisions of H. R. 7126 your committee may wish to consider two minor amendments of a clarifying nature. First, it is not clear from the present language of the bill whether the matching grant funds would be limited to the purchase of vaccine for eligible persons only. We assume that this limitation is intended, but a clarifying amendment relating to this point might be desirable. Second, on line 24 of page 3, it appears that the term "allotment percentage" should be substituted for the word "allotment."

In summary, we believe that the Federal grant assistance proposed in H. R. 6286, when combined with State, local, and voluntary funds, will be adequate to assure attainment of our national objective, and we would therefore reiterate our recommendation that this bill be enacted by the Congress.

The Bureau of the Budget advises that it perceives no objection to the submission of this report to your committee.

Sincerely yours,

ROSWELL B. PERKINS, *acting Secretary.*

EXECUTIVE OFFICE OF THE PRESIDENT,
BUREAU OF THE BUDGET,
Washington 25, July 8, 1955.

Hon. J. PERCY PRIEST,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington 25, D. C.

MY DEAR MR. CHAIRMAN: This is in reply to your letters of June 25, 1955, and June 29, 1955, requesting our views on H. R. 6973, a bill to protect the public health by providing for grants to assist States in assuring that no child is deprived of an opportunity for immunization against poliomyelitis because of

inability to pay the costs of vaccination, and for other purposes and H. R. 7026, a bill to provide for the purchase by the United States, and the distribution by the National Foundation for Infantile Paralysis, of a sufficient supply of poliomyelitis vaccine to immunize all children in the United States under 20 years of age against paralytic poliomyelitis and your request of July 6, 1955, for the views of the Bureau of the Budget on H. R. 7126, a bill to provide grants to assist States to meet the cost of poliomyelitis vaccination programs, and for other purposes.

H. R. 6973 is similar to H. R. 6286, which measure we advised the committee by letter dated June 15, 1955, would be in accord with the program of the President. However, H. R. 6973 does not provide for a limitation of the amounts authorized to be appropriated as is the case in H. R. 6286. Further, this proposal includes provisions for reimbursement to States for the costs of transporting children to central points for inoculation.

H. R. 7026 authorizes the National Foundation for Infantile Paralysis, under the supervision of the Secretary of Health, Education, and Welfare, to develop a vaccine allocation and distribution program, establish age and geographic priorities for the purpose of making the vaccine available to all persons under 20 years of age, and to regulate the vaccine to provide for its most effective use. The proposal authorizes the Secretary to purchase such supply of vaccine as may be necessary to carry out its provisions.

H. R. 7126 authorizes three types of Federal payments to States. The first, a formula grant based upon the income level of the State would provide for Federal payments for the purchase of vaccine for 25 percent of the unvaccinated eligible persons. Except in amount, this authority is similar to that of H. R. 6286 and would accomplish the objective of assisting the States in providing the vaccine for their low-income families.

In addition, however, H. R. 7126 would authorize Federal grants, on a 50–50 matching basis, for the cost of any additional vaccine purchased for vaccination of eligible persons by any State, its political subdivisions, or nonprofit organizations within its borders. The proposal also authorizes payment of an additional amount equal to 20 percent of the total grants awarded to each State for planning and conducting the State vaccination programs. The latter two features of this bill represent a significant departure from H. R. 6286.

In reporting our views on H. R. 6286, our letter stated that the objective of the grant program authorized by that measure was to assist the States so they might provide vaccine free of charge to their low-income families. To the extent that the provisions contained in these proposals authorize Federal payments which clearly go beyond this concept, they are not essential to the attainment of this objective.

Accordingly, this Bureau again recommends enactment of H. R. 6286, including the technical modifications proposed by the Department of Health, Education, and Welfare, instead of H. R. 6973, H. R. 7026, or H. R. 7126.

Sincerely yours,

ROWLAND HUGHES, *Director.*

(Thereupon, at 4:30 p. m., the committee was adjourned.)

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